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Safety Evaluation of Surgical Instruments

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Safety Evaluation of Surgical Instruments

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Declaration

I hereby declare that this thesis titled “Safety Evaluation of Surgical Instruments”, submitted to University of Dundee for the degree for Doctor of Philosophy is a record of the original work completed by myself and that it has not previously been accepted for a higher degree at this University or any other institution of learning.

Signature: _____ Date:

Yunwei Xu

Statement by Supervisor

I, Zhihong Huang, have read this thesis titled “Safety Evaluation of Surgical Instruments” and certify that the conditions of Ordinance 39 of the University of Dundee have been fulfilled.

Signature: _____ Date:

Prof. Zhihong Huang

Abstract

Spurred by recent press reports and other concerns this thesis focuses on the quality of surgical instruments. The current situation is reviewed by considering the regulatory framework and by investigating the quality of newly purchased instruments. A range of test protocols based on British Standards and best practices from industry were developed. These were designed to be practical in the real world situation and a user-friendly database was built to collate all the relevant data and inform the Supply Chain.

The conditions experienced by instruments during their lifetime in the health care environment, especially in cleaning and disinfection were studied and as many instruments implicated in Incidents as possible investigated to understand the possible root causes of failure.

During this work the importance and debate over surface finish, passivation and disinfection processes became apparent and research was carried out into the effect on wettability and drying mechanism of passivation and repeated disinfection cycles on various typical surface finishes. This concentrated on the environment within the health service unlike other studies which have been concerned with more aggressive industrial situations.

Standards and Procedures on the care of instruments have been established in order to improve the current management of surgical instruments and to ensure that they are and remain fit for purpose.

Glossary

Symbols

f_{sl}	Contact area fraction of solid/liquid interface	Ra	Roughness
f_{sv}	Contact area fraction of solid/vapour interface	θ	Contact angle (on ideal surface)
r	Non-dimensional surface roughness factor	θ_w	Contact angle (Wenzel state)
γ_{lv}	Surface tension at the interface of liquid/vapour	θ_{CB}	Contact angle (Cassie-Baxter state)
γ_{sl}	Surface tension at the interface of solid/liquid	θ_{sl}	Contact angle fraction of solid/liquid interface
γ_{sv}	Surface tension at the interface of solid/vapour	θ_{sv}	Contact angle fraction of solid/vapour interface

Acronyms

ABHI	Association of British Healthcare Industry	BSI	Bloodstream Infection
AORN	Association of periOperative Registered Nurses	CCA	Constant Contact Angle
BS	British Standard	CCR	Constant Contact Area
BSE	Bovine Spongiform Encephalopathy	CEN	The European Committee for Standardization

CJD	Creutzfeldt-Jakob Disease	IRIC	Incident Reporting and Investigation Centre
CSSD	Central Sterile Service Department	ISO	International Organization for Standardization
EDS	Energy Dispersive Spectroscopy	MCU	Microcontroller Unit
EEG	Electroencephalogram	MHRA	Medicines & Healthcare Products Regulatory Agency
fCJD	familial CJD	MOSFET	Metal-Oxide-Semiconductor Field-Effect Transistor
FDA	Food and Drug Administration	MRSA	Methicillin-Resistant *Staphylococcus Aureus*
FSN	Field Safety Notice	NSIRC	National Surgical Instrument Reference Centre
GD-OES	Glow Discharge Optical Emission Spectroscopy	PID	Proportional-Integral-Derivative
GEM	Global Energy Minimum	RO	Reverse Osmosis
HAI	Healthcare-Acquired Infections	sCJD	sporadic CJD
HAP	Hospital-Acquired Pneumonia	SEM	Scanning Electron Microscope
hFE	Minimum Amplification Factor	SHTM	Scottish Health Technical Memorandum
HFS	Health Facility Scotland	SMTL	Surgical Materials Testing Laboratory
hGH	Human Growth Hormone	SSI	Surgical Site Infection
iCJD	iatrogenic CJD	TSEs	Transmissible Spongiform Encephalopathies

UDF	Unretrieved Device Fragment
UDI	Unique Device Identification
UTI	Urinary Tract Infection
VAP	Ventilator-Associated Infection
vCJD	variant CJD
XRD	X-ray Diffraction

Chapter 1 Introduction

1.1 Motivation

The quality of surgical instruments is fundamental for patient safety. They must be well designed and well made so that they are as easy to use as possible and deliver the required precision. Substandard manufacture can make surgical instruments dangerously inefficient, fail mechanically in use or leave dangerous shards of metal in the patient tissue.

In the past several decades, the safety and reliability of reusable surgical instruments can only rely on the assumption that new instruments should be of assured quality, with manufactures' information provided when purchased under related standards.

Barts and London NHS trust was the only place in the UK who carried out an inspection study in 2004, which lasted for 6 months. Results show that with 4800 new instruments examined, 15% are considered substandard according to related British Standards. Identified flaws included absence of manufacturer's name, machining burrs and debris in teeth, cracks, failure of correct meshing of ratchets, soldering faults, and corrosion [1].

On the other hand, good quality surgical instruments, with proper care, are expected to have a lifespan of more than 10 years [2]. However, some surgical instruments are reported broken or corroded shortly after purchase.

Corrosion on surgical instruments provides a seat for contamination, allows entrapment of debris and prevents proper sterilisation [2]. Corrosion can also compromise the structural integrity of instruments and lead to mechanical failure in use. Among the 730 instruments failing Bart's inspection, 28 (3.8%) had severe problems related to corrosion [1, 3] . Examples are illustrated in Figure 1.1.

Figure 1.1 Corrosion deposit (left) and stress corrosion cracking (right) found on newly purchased instruments [3]

Broken instruments raise the risk of Unretrieved Device Fragments (UDFs). These are especially dangerous as their free movement within a patient's body may cause life-threatening problems such as infection, local tissue reaction or embolism among others. Problems caused by UDFs can have a long incubation period before being noticed, sometimes years during which, the UDF may move freely inside the patient's body and might cause internal bleeding if near a blood vessel, injury if near a vital organ or burns due to heating up during MRI scans. Over 1000 Incidents related to UDFs are reported to the US Food and Drug Administration (FDA) each year [4, 5]. In one particularly adverse event analysis [6] related to guidewires used during surgery. 19 (4%) fatalities were reported among 466 reports while 204 (44%) reported injury. 66% of the events reported were due to guidewire breakage. Moreover, to identify the UDF inside the body is very costly. It involves much paper work on reducing the possible occurrence, scanning check for all patients, surgeon and nurses' effort and remedial surgery.

Incidents are reported through Incident Reporting and Investigation Centre (IRIC) in Scotland and Medicines and Healthcare products Regulatory Agency (MHRA) in England. The purpose of these reporting systems is to alert to products flaws during and initiate appropriate actions on all similar products available on the market. There is a high incidence of under reporting of Incidents in particular related to surgical instruments. This can be variously due to the comparative low cost of each instrument, perception that Incident is an "one off" event, staff pressures, doubt over who is responsible for reporting and over the definition of an "Incident".

Even then there were still as many as 62 Incidents relating to surgical instruments reported through IRIC from 2009 to 2013 [7]. Incidents include corrosion with short-term service, fractures/breaks and function failure during use. Two Incidents left instrument fragments in the patient which required further surgery for retrieval. From January 2008 to May 2010, NHS Tayside had "eight objects, including the tip of a guide wire and the tip of a needle, were left inside patients during surgery", [8]. Luckily, none of the patients was injured due to these Incidents.

With the selection of surgical instruments available, health authorities find it hard to decide on a balance between quality and price. Opinions both of users and manufacturers vary widely on the need, benefits and disadvantages of reflection-reduced surface finishes. It is suspected that a polished surface can cope with the decontamination cycle better as a mirror-like surface does not hold moisture. Some others prefer reflection-reduced instruments due to their better feel and appearance quite apart from their reduced reflection.

There is also increasing concern regarding alkaline detergent used in Central Sterile Services Department (CSSD). According to Spry [2], strongly alkaline detergents are not recommended for routine processing as "they can destroy the passivation layer and promote corrosion". However, alkaline detergents have been proven to be effective in minimizing prion transmission risks [9] and this is a primary reason they are widely used across the UK.

Therefore, it is important to fully understand the root causes of failure. Is it all because of poor manufacturing or is it due to the inappropriate actions during use?

1.2 Objectives

The main objectives of this project are:

1. To review the surgical instruments' quality in Ninewells Hospital;
2. To review the regulatory requirements of surgical instruments;
3. To investigate the state of compliance among major suppliers;
4. To investigate the modes of failure;
5. To investigate the need of setting up a quality inspection program for surgical instruments in Scotland;

6. To study the effect and corrosion resistance of different surface finishes and surgical grade stainless steels by looking at such as wettability, evaporation mechanism and Chromium enrichment level;
7. To study the effect of passivation and standard clinical disinfection processes on surgical instruments;

1.3 Contribution

This thesis contributes in several areas:

1. Demonstrates the high substandard rate of purchases surgical instruments of Ninewells Hospital and proves the quality issue of new instrument is a national problem;

2. Raises awareness of surgical instruments, pointing out the urgent need of establishing an inspection service for instruments;

3. Successfully establishes an operable test protocol based on British Standards and a database to record and analyse instrument related information;

4. Successfully eliminates the suspicion of the aggressiveness of disinfection cycles;

5. Demonstrates the differences among surface finishes commonly applied on surgical instruments and gives recommendations on preferred finishes;

The following paper has been published:

1. Yunwei Xu, Zhihong Huang, George Corner, (2016) “A study of the effect of clinical washing decontamination process on corrosion resistance of Martensitic Stainless Steel 420”, Bio-Medical Materials and Engineering 27(4):341-351.

Six reports have been issued to various health facilities across the UK regarding incidents and failures of surgical instruments. However due to confidentiality, detailed information of these facilities cannot be published. Several incidents of interest are included in this thesis without mentioning facility names.

1.4 Chapter Summaries

Chapter 2 gives an introduction to the infection risk in healthcare facilities through instruments, the role of surgical instruments among all types of medical devices, the related Standards and guidelines of the decontamination processes. The factors contributing to the motivation of this study are highlighted as well.

Chapter 3 describes the environment in which surgical instruments are purchased, used and processed. The philosophy of the test protocol developed and database designed is presented. Results obtained by inspecting newly purchased and designed instruments are described and analysed. An overview of the quality of purchased instruments and the state of compliance among major suppliers are featured.

Chapter 4 presents four case studies related to surgical instrument Incidents and failures. The root causes of each case are studied and analysed. A summary of instrument failure modes is given.

Chapter 5 describes the effect of various factors on surgical instrument behaviour. The factors include material type, surface roughness, passivation and disinfection processes. The initial experiment presented gives more research directions for the main experiment. How these factors influence the surgical instruments behaviour is analysed.

Chapter 6 summarises the conclusions obtained in the previous chapters. Both the contribution and the limitation of this study are discussed to give directions for future research.

Chapter 2 Background

2.1 Healthcare Acquired Infections

Even before the establishment of the germ theory of infection, Florence Nightingale (1820-1910) had promulgated the idea that no further harm shall be done to patients when they are in a hospital. She improved the social hygiene in the war hospitals. Nurses were asked to wash hands repeatedly; fresh bed sheets and bandages were supplied from a separate laundry; the hospital walls, floors and ceilings were scrubbed. Her significant contribution in cleanliness is still celebrated world-wide today and considered to have a profound impact on the modern healthcare system.

Although the idea of keeping patients from harm was brought up even before Christ and has been passed on generation by generation in the form of the Hippocratic Oath, the clear definition of medical harm was not completed till twenty-first century [10].

Healthcare Acquired Infection (HAI) [11] is defined as an adverse event where such infections "are not present at the time the patient's healthcare begins, but arise afterwards". Infections appearing after discharge and occupational infections among staff are also counted as HAI.

Types of HAI include overall HAI, urinary tract infection (UTI), surgical site infection (SSI), hospital-acquired pneumonia (HAP), ventilator-associated infection (VAP), and health care-associated bloodstream infection (BSI). It has been shown that HAI is very costly to healthcare services and to patients, but avoidable through effort.

HAI is the most frequent adverse event threatening patient safety world-wide but especially in developing countries. Reports published [12, 13] show that the prevalence of HAI in developing countries is 15.5%, and in developed countries 7.6%. The UK's prevalence rate is 9% - significantly above average for the developed countries.

A comprehensive survey in Scotland between October 2005 and October 2006 included all acute hospitals and a representative numbers of non-acute hospitals. Results

indicated that the overall prevalence was 9.5% for acute hospitals and 7.3% for non-acute hospitals. The most common type of HAI observed was UTI with 17.9% of total, followed by SSI of 15.9%. Costs due to HAI in Scotland were estimated to be £183 million per annual according to the survey [11].

2.1.1 Multidrug-resistant Organisms

As early as the 1880s, diseases caused by *Staphylococcus Aureus* were observed by Ogston. In the following 100 years, not only was it not eliminated, but became a rising concern as HAI. This is due to the emergence of multidrug-resistant strains and the difficulties in treating them. One typical type of such organism is methicillin-resistant *Staphylococcus Aureus* (MRSA) [14, 15], commonly known as a superbug.

The most possible spread of MRSA is through skin contacts while it can also spread through contaminated objects and surfaces. The diseases caused by MRSA [16] range from mild infections to serious diseases such as sepsis. Moreover, the infections are likely to become chronic. A surveillance [17] of MRSA carried out in Europe between 1999 and 2002 pointed out that among all patients with HAI, the proportion of MRSA was the highest (35%) and the UK is listed in one of the highest proportioned countries, at 41.5%.

The treatment of multidrug-resistant organism infection usually uses various types of antibiotics, depending on the infection site and organism type. Moreover, there are fewer and fewer antibiotics effective against the new emerging organism types. To prevent the occurrence of multidrug-resistant organism infection, it is important to thoroughly disinfect the environment and the instruments.

2.1.2 Creutzfeldt-Jakob Disease

Creutzfeldt-Jakob Disease (CJD) is a form of neurodegenerative disorder affecting humans and sharing clinical features with an animal disease, transmissible spongiform encephalopathies (TSEs). It is called spongiform because it degenerates brain tissues and leaves discernible holes in the central nervous system. Figure 2.1 is a light photomicrograph of brain tissue, illustrating the characteristic pattern caused by CJD.

CJD was first identified in the 1920s by two German neurologists and thus named after them [18-20]. The neuropathology and epidemiology remained unclear, due to unique features of each case and factors such as the transmissible agent involved until the well-known mad cow disease outbreak in the 1980s [19].

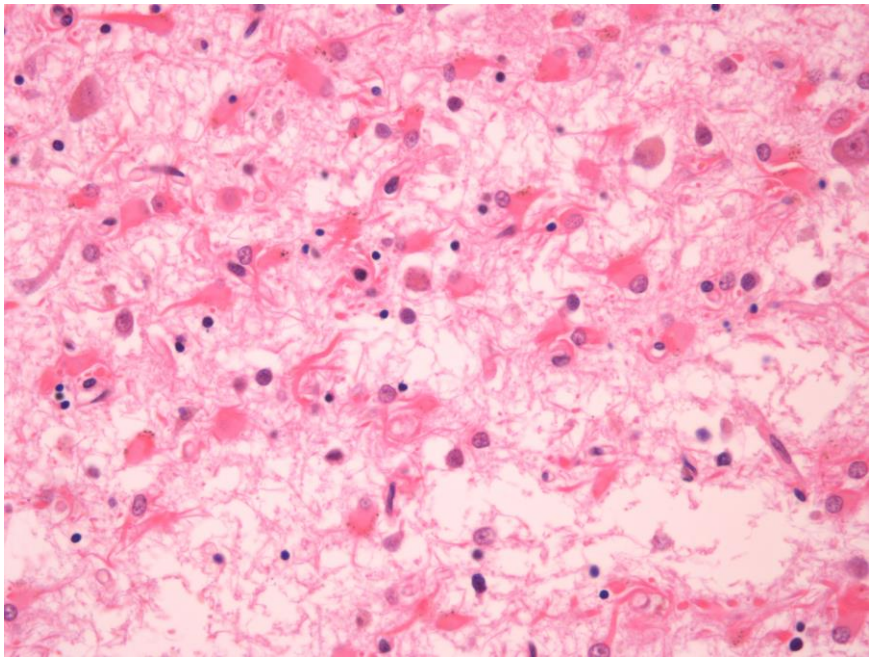


Figure 2.1 Severe Spongiform Vacuolation in CJD (Courtesy of [21])

Four types of CJD are currently known, sporadic, variant, familial (inherited) and iatrogenic CJD [19]. Although having different causes, all forms of CJD follow a fatal path after initial symptoms such as dementia and ataxia. Types of CJD are briefly described below. A direct comparison among four CJD types can be seen in Table 2.1.

Sporadic CJD (sCJD) [22] is most prevalent among the four types, with a proportion of 85-95%. It is randomly distributed all over the world, with approximately 1 case per million of the human population per year. sCJD is the only idiopathic occurring form of CJD and thus its exact cause remains unknown. However no evidence has pointed to diet, surgery or blood transfusion. It usually affects people of middle to old age, and shows a rapid progress with only several months of median survival. Six subtypes [20] have been determined according to the amino acid, methionine or valine, involved.

After bovine spongiform encephalopathy (BSE) being identified in 1986, potentially infected animals were excluded from the food chain in 1988 [23], variant CJD (vCJD) was first discovered in 1995 and reported in 1996 in the UK [24, 25],

followed by a rising number of reported cases in the following 5 years (Figure 2.2). The total number of deaths in the UK due to vCJD reached 177 up to July 2015 [26]. Compared to sCJD, vCJD affects younger aged people (under 42 years-old). It also has a longer incubation period (sometimes decades) and slower progress with more than a year of survival [20]. Yet it was not until 2003 and 2006 when three secondary vCJD patients were identified [27] that the possibility of transmission between patients was realised.

Familial CJD (fCJD) was first recorded in 1924 and studied in 1930 [28]. It accounts for a small portion of all CJD cases and is related to the genetic mutation of prions. More than 30 mutations affecting the prion have been discovered till 2013 [25]. The onset of fCJD is earlier than sCJD while the survival time longer [20].

Both sCJD and vCJD can be transmitted between patients by contact with infected agents, such as human growth hormone (hGH), transplants, blood products and surgical instruments [18, 29, 30]. CJD acquired in such way is defined as iatrogenic CJD (iCJD), although sometimes categorised as secondary vCJD.

Up to July 2015, 79 cases of iCJD death have been reported in the UK [26]. The actual number of iCJD cases is considered to be higher than recorded since some might still be under incubation period with no symptoms and thus not brought to attention.

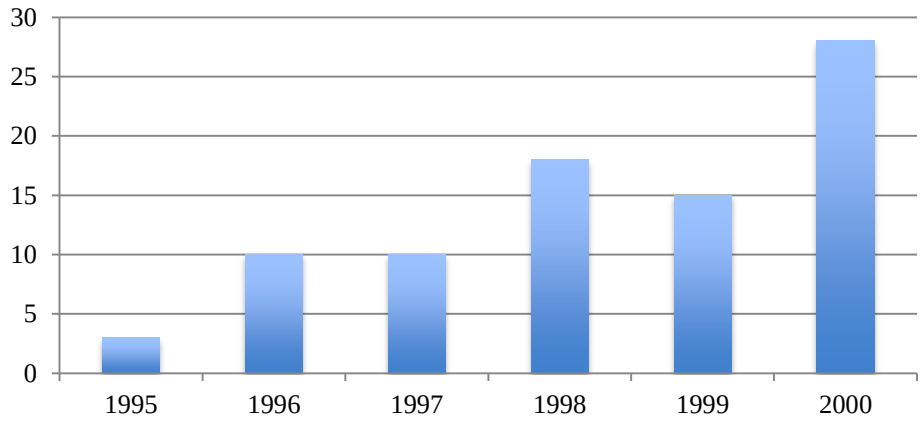


Figure 2.2 Deaths from vCJD in the UK between 1995 and 2000 (Adapted from [26])

Up to 2006, at least 10 surgical procedure related iCJD cases were identified in the UK, among which 3 were directly caused by surgical instruments [31]. Research carried out validated prion's resistance to conventional decontamination processes, yet the minimum infection dosage remains unknown. Shortly after then the UK government

issued a guidance [32] to prevent further secondary transmission, requiring:

"A separate pool of new neuro endoscopes and reusable surgical instruments" to be used for "children born since 1 January 1997". Moreover, certain high-risk surgeries, such as tonsillectomy and adenoidectomy, have been asked to use disposable surgical instruments [33].

As a consequence of the urgent regulations published in 2006, a massive amount of new surgical instruments were purchased within a short period of time and since then the quality issue of surgical instruments has come to public awareness. With patients born after 1997 turning adults, risk of being exposed to contaminated surgical instruments has arisen in adult theatres and further large purchases are being made. Several hospitals who tried single-use instruments opted to use reusable surgical instruments again for tonsillectomy because of quality and cost issues.

As a result, immediate attention is required to assure the quality of new surgical instruments being purchased.

	Aetiology	Transmission	Distribution	Incubation Period	Onset Age	Survival Time	Possible Clinical Features	Deaths[A]
sCJD	Idiopathic	–	Random	–	65	4 months	Myoclonus Visual disturbance Cerebellar disturbance Pyramidal dysfunction	1632
vCJD	Acquired	BSE	UK	8 years	28	14 months	Psychiatric disorder Painful sensory symptoms Cerebellar ataxia Cognitive impairment	177
fCJD	Genetic	–	Random	From birth	58[B]	6 months[B]	Cerebellar ataxia Late cognitive features Autonomic disturbances	173
iCJD[C]	Acquired	hGH Transplants Blood products Instruments	UK US France Japan	11 – 15 years	–	–	–	79

Table 2.1 Comparison of CJD types [20, 22, 25, 26, 28]

* Incubation period, onset age and survival time in the table are all median numbers

A UK death number till July 2015

B Median number of the commonest fCJD type, $CJD^{E200k\text{-}129M}$

C All features of iCJD depends on the age and form of CJD patient exposed to

2.2 Surgical Instruments

A surgical instrument is any specifically designed for a surgical procedure, to complete a specific action or assist in a surgical procedure. Surgery by its nature remains a dexterous skill and is often learned from masters of the craft [34]. Individual surgeons tend to keep to their own way of performing a procedure. This has helped to create the huge variety of different surgical instruments and has driven evolution in design. There is further variation in single use and re-usable instruments in a variety of materials: stainless steel, titanium and plastic.

2.2.1 Origin and History of Surgical Instruments

Humans first learned to treat injuries by using the mouth to suck out stings, hands to stop bleeding and teeth to finish amputation [35]. Before long, they realised that appropriate tools could dramatically improve the treatment efficiency and outcome. Natural materials such as animal teeth and bamboo were then used to provide a cleaner cut. With the discovery of copper, bronze and iron, surgical tools were manufactured with great functionality, better precision and durability.

	Mouth	**Teeth**			**Thumb**	**Nail**	
Action	Suck	Bite	Grind	Clench	Compress	Cut	Scrape
Instrument	Aspirator	Rongeurs	Saw	Clamp	Tourniquet	Scalpel	Rasp
	Finger					**Fist**	
Action	Hook	Probe	Retract	Dilate	Pinch	Grasp	Hammer
Instrument	Hook	Probe	Retractor	Speculum	Spring Forceps	Clamp	Mallet

Table 2.2 possible links between natural actions and instruments [36]

Although not evidenced, it is reasonably suspected that some surgical instruments were initially invented to mimic human actions, such as grasping, compressing and cutting. Table 2.2 illustrates some modern instruments possibly derived from such actions [36].

2.2.2 Role of Surgical Instruments

In 1968, Earle H Spaulding produced a classification of patient care related equipment. This classification system is based on a rational judgment of the items' risk in infection transmission and is still used today. According to the classification, patient care items can then be subjected to an appropriate level of decontamination. The three defined categories are critical, semi-critical and non-critical [37-39].

Critical items [38] include surgical instruments and implants which are in direct contact with tissue and could cause transmission of disease. These items must be both high-level disinfected and sterilised between each use. Liquid chemical disinfectant is used in compliance with instructions for concentration, contact time and temperature. All microorganisms including bacterial spores require to be destroyed for sterility.

Semi-critical items [38] include respiratory therapy equipment and diaphragm fitting rings, which are in contact with mucous membranes or non-intact skin. Such items should have no trace of microorganisms and only a small number of bacterial spores. High-level disinfection is required for semi-critical items.

Noncritical items [38] include blood pressure cuffs and bedside tables, which only contact intact skin. Cleaning or low-level disinfection is sufficient.

While surgical instruments are categorised in the most rigorous group according to Spaulding's classification; they are defined as the least controlled group by the European Commission.

The guidance published by Department of Health [40] defines medical devices into three major groups (Class I, Class II (a&b) and Class III) according to their risk of harm to the patient within their intended use. The purpose of this classification is to reduce risks by applying the appropriate level of control.

Various criteriae such as duration of contact with the patient body and degree of invasiveness are used to grade. Duration is categorised into three levels: transient (less than 60 minutes), short term (no more than 30 days) and long term (more than 30 days). The degree of invasiveness is grouped into non-invasive, invasive in a naturally existing body orifice and surgically invasive devices.

Although repeatedly used, surgical instruments are usually operated on patients

for periods of minutes or less each time. Moreover, most surgical instruments do not have an energy supply and do not give off radiation. They are (or should be) used and operated only by trained surgeons. This places them in the category of transient use, surgically invasive devices.

As Class I devices, reusable surgical instruments require only self-declaration for CE mark compliance, the threshold level for manufacturing such devices is thus comparatively low and this results in poor regulation and products with mixed quality available on the market. There has been an ongoing discussion regarding if Class I is indeed appropriate for surgical instruments.

2.3 Standards

Standards are technical documents drafted and published by recognised bodies. They act as an interpretation of legal requirements and generally offer a route to compliance with the relevant requirement of quality and safety.

2.3.1 Types of Standards

There are four types of standards applicable: private, European, international and national. Private standards are developed for specific internal commercial purposes, thus not normally publically available.

The relationship of European, international and national standards is introduced by Bancroft [41]. European (EN) standards are developed by the European Committee for standardization (CEN) while International (ISO) standards are published by International Organization for Standardization (ISO). CEN and ISO publish standards on the same level but cover different scopes of countries. In the Vienna Agreement, the two bodies agreed to approve each other's Standards to avoid redundancy, duplication and conflict. When an ISO standard is adopted by CEN, the standard is labelled EN ISO and it is called a *Harmonised Standard*.

National standards are adapted from either EN standards or ISO standards by adding country abbreviation in the front of EN / ISO. For example, the name of a British Standard originating from an ISO standard to suit British legal requirements starts with BS ISO.

EN standards form the basic legal requirements across the EU members. This is usually written in a non-specific and general language. From European Directives, to EN standards, to national standards, to Guidance documents and at last to local procedures, the documents cover smaller scopes and therefore have a more specific language. All documents point to the *Essential Requirements* with either voluntary or mandatory routes.

The most relevant standards to read here are the British Standards, because they are adapted from either ISO standards or EN standards are incorporated into the British law.

2.3.2 Standards Relating to Surgical Instruments

The first relevant British Standards date back to the 1980s. They are drafted by ISO and adapted by EN and BS. Table 2.3 illustrates some details of the British standards related to surgical instruments.

BS EN ISO 7153 consists of four parts, which cover differing scopes of instruments and foci. They all provide the basic requirements for manufacture.

Part 1 [42] was first published in 1991 and amended in 2001. It regulates the grades of stainless steel used to manufacture surgical and dental instruments. 17 types of stainless steel are listed, named from A to S (excluding J and Q). The chemical compositions of all steel types are listed with tolerances in Table 2.4.

Part 2 [43] covers the detailed specifications of non-cutting instruments such as artery forceps, needle holders, retractors and other instruments with pivot joints. Criteriae include materials, hardness, surface condition, corrosion resistance, packaging, marking, elasticity and functions.

Part 3 and Part 4 [44, 45] are similar to Part 2, but cover specifications of dissecting forceps and cutting instruments such as scissors.

Standard	Equivalence	Document Title	First Published	Current Edition
BS EN ISO 7153 - 1	BS 5194	Surgical Instruments – Metallic materials – Stainless Steel	1991	2001
BS EN ISO 7153 - 2	BS 5194	Surgical Instruments – Specification for instruments with pivot joints (excluding cutting instruments)	1989	-
BS EN ISO 7153 - 3	BS 5194	Surgical Instruments – Specification for dissecting forceps	1985	-
BS EN ISO 7153 - 4	BS 5194	Surgical Instrument – Specification for scissors, shears and other jointed cutting instruments	1985	-
BS EN ISO 13402	BS 7891	Surgical and Dental Hand Instruments – Determination of Resistance against autoclaving, corrosion and thermal exposure	1997	2001
BS EN ISO 17664	-	Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004	-

Table 2.3 Details of surgical instruments related British Standards [42-47]

		Chemical compositions, %								
Grade	**Type**	**C**	**Si**	**Mn**	**P**	**S**	**Cr**	**Mo**	**Ni**	**Other**
A	Martensitic	0.09 – 0.15	1 max	1 max	0.04 max	0.03 max	11.5 – 13.5	–	1 max	–
B	Martensitic	0.16 – 0.25	1 max	1 max	0.04 max	0.03 max	12.0 – 14.0	–	1 max	–
C	Martensitic	0.26 – 0.35	1 max	1 max	0.04 max	0.03 max	12.0 – 14.0	–	1 max	–
D	Martensitic	0.42 – 0.50	1 max	1 max	0.04 max	0.03 max	12.5 – 14.5	–	1 max	–
E	Martensitic	0.47 – 0.57	0.5 max	1 max	0.03 max	0.025 max	13.7 – 15.2	–	0.5 max	–
F	Martensitic	0.60 – 0.70	0.5 max	1 max	0.03 max	0.025 max	12.0 – 13.5	–	0.5 max	–
G	Martensitic	0.65 – 0.75	1 max	1 max	0.04 max	0.03 max	12.0 – 14.0	0.50 max	1 max	–
H	Martensitic	0.35 – 0.40	1 max	1 max	0.045 max	0.03 max	14.0 – 15.0	0.40 – 0.60	–	V: 0.10 – 0.15
I	Martensitic	0.42 – 0.55	1 max	1 max	0.045 max	0.03 max	12.0 – 15.0	0.45 – 0.90	–	V: 0.10 – 0.15
K	Martensitic	0.33 – 0.43	1 max	1 max	0.03 max	0.03 max	15.0 – 17.0	1.00 – 1.50	1 max	–
L	Ferritic	0.08 max	1 max	1.5 max	0.06 max	0.15 – 0.35	16.0 – 18.0	0.60 max	1 max	–
M	Austenitic	0.07 max	1 max	2 max	0.045 max	0.03 max	17.0 – 19.0	–	8.0 – 11.0	–
N	Austenitic	0.12 max	1 max	2 max	0.06 max	0.15 – 0.35	17.0 – 19.0	0.70 max	8.0 – 10.0	–
O	Austenitic	0.15 max	1 max	2 max	0.045 max	0.03 max	16.0 – 18.0	–	6.0 – 8.0	–
P	Austenitic	0.07 max	1 max	2 max	0.045 max	0.03 max	16.5 – 18.5	2.0 – 2.5	10.5 – 13.5	–
R	Martensitic	0.85 – 0.95	1 max	1 max	0.045 max	0.03 max	17.0 – 19.0	0.90 – 1.30	–	V: 0.07 – 0.12
S	Martensitic	0.60 – 0.75	1 max	1 max	0.04 max	0.03 max	16.0 – 18.0	0.75 max	–	–

Table 2.4 Chemical compositions of surgical grade stainless steels [42]

BS EN ISO 13402 [47] specifies three methods to test the corrosion resistance of surgical instruments using either autoclave, boiling water or copper sulphate. The purchaser or the manufacturer can choose to apply either one or two of the tests described in the standards on placing an order. The test methods are described in BS EN ISO 7153 Part 2 – 4 [44, 45, 48] as well.

BS EN ISO 17664 [46] specifies the information to be provided by manufacturers such as reprocessing instructions with limitations, cleaning method, disinfection method, drying details, sterilization method, storage conditions, packaging requirements and Risk Assessment.

2.4 Decontamination Process

The decontamination process is essential to safety of staff and patients. It is key to reduction of the number of HAI [33].

Decontamination is a complex process consisting of many steps, the three most important being cleaning, disinfection and sterilization. Most parts of the decontamination process are generally carried out in a central facility although others are done elsewhere, such as transportation and storage (Figure 2.3).

Cleaning is a physical process which removes visible organic debris and helps to ensure the effectiveness of disinfection. Ultrasonic cleaners can be used as an additional part of the process.

Disinfection [37, 39] is defined as "a process used to reduce the number of microorganisms to a level which is not harmful to health at the site of use". However, unlike sterilization, elimination of bacterial spores is not achieved in disinfection. Disinfection is a very significant step in decontamination process because it prepares the instruments for the following sterilization ensuring the desired penetration can be achieved.

Sterilization is the most critical part of decontamination and is carried out after disinfection. It destroys all living organism including spores and therefore ensures the safety of patient care items, such as implants. However, it has been shown recently that not all forms of life are destroyed, particularly CJD prions.

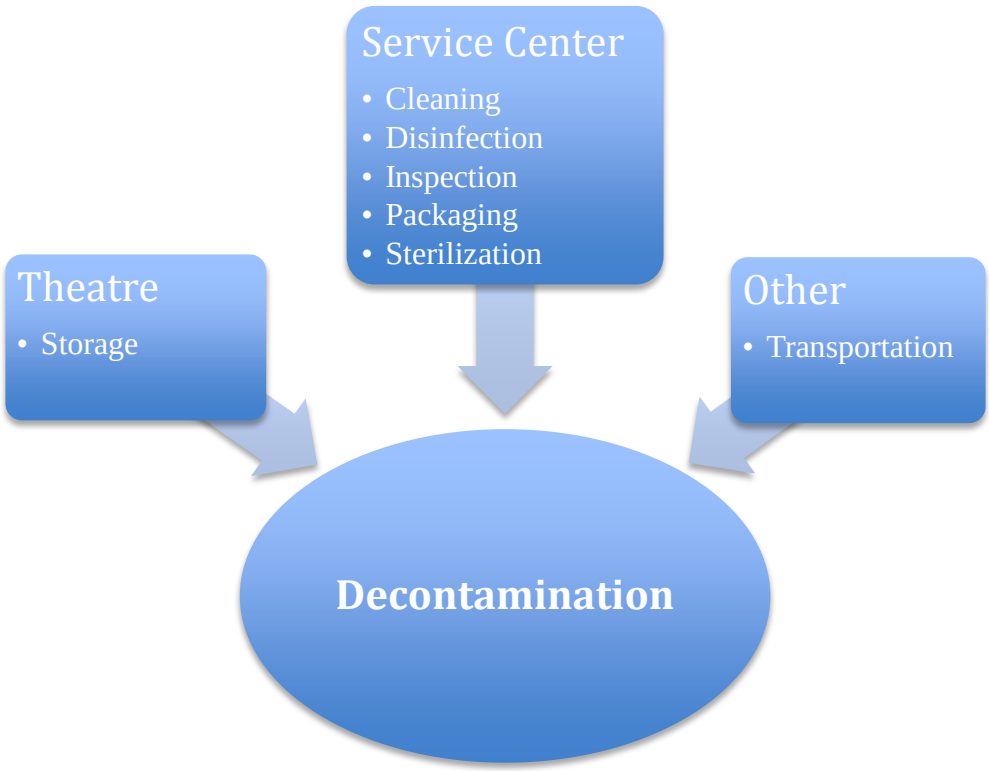


Figure 2.3 Decontamination steps divided by locations (Adapted from [37])

2.4.1 History of the Decontamination Process

Joseph Lister (1827-1912) is considered the father of surgical instruments decontamination. After years of observation, Lister realised that infection might be caused by 'the germs that float in the air'. Therefore he tried undiluted carbolic acid, the most effective antiseptic known then, on patients to create a barrier between patients and environment. He also extended the decontamination process to surgical instruments. Although carbolic acid proved to be harmful to human tissue, Lister [49, 50] successfully decreased the mortality rate of surgery in Glasgow from 39.1% to 9%.

The use of disinfectants can be traced back to food preservation, where salt was used to delay meat putrefaction. Halogens, such as chlorine, iodine and bromine proved to be very active disinfectants and were therefore used for surgical instruments. Neutralisers such as ammonium chloride were introduced to prevent the over activity of the disinfectant.

Robert Koch (1843-1910) tried use an oven to kill bacterium after Louis Pasteur's (1822-1895) work on pasteurisation [51]. Although he came to the conclusion that most

bacterium and spores can be destroyed at high temperatures, it took him 1.5-4 hours to achieve the result at every attempt. This is due to the low penetration of dry heat. By combining his method with John Tyndall's (1820-1893), in which boiling was used to achieve a germination state for spores, Koch managed to achieved the same results in a more reasonable time. However pressure was not measured.

It was not until 1950s that the sterilization methods took a further step forward. Not only steam was used, but also air was eliminated so as to achieve a higher pressure and a desirable temperature. Both temperature and pressure were measured in the autoclave.

However, heat sensitive items such as Electroencephalogram (EEG) electrodes were only decontaminated by ethanol and formaldehyde vapour in UK hospitals and several cases of CJD transmission via surgical instruments were reported. After realizing the decontamination procedure used then were not adequate, sodium hydroxide and sodium hypochlorite were suggested as disinfectant. Yet before long these disinfectants' corrosive nature was obvious [33]. New suggestions and guidelines were then published to prevent as many disease transmissions as possible, along with studies and reviews carried out to keep decontamination process effective. The Standards and guidelines currently in used are introduced below.

2.4.2 Standards and Guidelines

Among patient care items which repeat usage is required, reusable surgical instruments have the highest requirement of decontamination. All three steps of cleaning, disinfection and sterilization must be performed each time after use to be ready for the next case.

Standard	Part	Document Title	Published
SHTM 2010	1 of 6	Overview and management responsibilities Sterilization	2001
	2 of 6	Design considerations Sterilization	
	3 of 6	Validation and verification Sterilization	
	4 of 6	Operational management Sterilization	
	5 of 6	Good practice guide Sterilization	
	6 of 6	Testing and validation protocols Sterilization	
SHTM 2030	1 of 3	Design considerations Washer-disinfectors	2001
	2 of 3	Operational management Washer-disinfectors	
	3 of 3	Validation and verification Washer-disinfectors	
SHTM 2031	1 of 1	Clean Steam for sterilization	2001

Table 2.5 List of SHTM standards [52-61]

Although local procedures vary, certain requirements in the Standards and guidelines must be met. Related advisory guidelines published by NHS Scotland, Scottish Health Technical Memorandum (SHTM) [52-61], are listed in Table 2.5. Points worth noting are described as below.

A cold wash is first be applied with water less than 35°C, followed by a hot wash with water more than 55°C. Rinse and thermal disinfection are also required after the main wash. A one-second final rinse at 90°C, a one-minute final rinse at 80°C and a three-minute final rinse at 71°C are treated as equivalent and effective [62].

High-temperature steam [52] is most often used for sterilization due to its "superior performance". An equivalent chart indicating effective sterilization cycles with different temperature/time relationship is described below (Table 2.6).

Equivalences	**1**	**2**	**3**	**4**
Sterilization Temperature (°C)	115	121	126	134
Maximum Temperature (°C)	118	124	129	137
Minimum time (min)	30	15	10	3

Table 2.6 Effective high-temperature steam sterilization procedures [52]

A minimum of 2 independent sensors are required for each parameter. Time, temperature and pressure (where necessary) data shall be recorded numerically and the records stored [63]. Recommended practices for cleaning and caring for surgical instruments are reviewed and published in Association of peri Operative Registered Nurses (AORN) Journal. Points mentioned include [64-67]:

a) Instruments must be kept free of organic debris during surgery and moist afterwards. A damp towel should be used to prevent blood drying out on surgical tools.
b) The decontamination process must be carried out in as short time as possible.
c) Instruments need to be taken care of by putting heavy ones on the bottom of the tray and light ones on top.
d) Delicate instruments and tools with sharp edges need to be separated and protected.
e) Function of instruments should be checked after disinfection.
f) Lubrication should be applied where required.

2.4.3 Current Methods of Decontamination Process

As Standards and guidelines are not mandatory, guidelines are adapted to local procedures [41]. The procedure adopted at the CSSD in Ninewells Hospital and Medical School, Dundee is taken as an example. This is a large central unit, was convenient to access and the staff provided support and advice.

Instruments sets opened during surgeries are sent to CSSD for decontamination. All instruments in the opened set, no matter whether used or not, must be reprocessed. Theatre staff dissemble all parts of surgical tools and open any box joints.

After the instrument trays are delivered to CSSD, the label on each tray is scanned to record its location and status. During the whole decontamination procedure, this particular label will be scanned at each stage to renew its status.

Cleaning is usually the first step. Here organic debris and blood are scrubbed off in a sink. *Serquat Instrument Cleaner Concentrate* (Serchem: Telford, UK) is used as a detergent in this step. However, cleaning is not a mandatory step and is often skipped when CSSD processes are overloaded.

Before instrument trays are put into washer-disinfectors, all instruments are put in an open state where relevant. The disinfection procedure contains several steps such as cold rinse, hot wash, disinfection and drying. Detergent used in this stage is *Maximum pH Plus* (Serchem: Telford, UK), with a pH value of 13-14. Reverse Osmosis (RO) water is used for disinfection. It is a type of water that is purified to eliminate all ions, molecules and particles by using a semipermeable membrane and an applied pressure. The detailed procedure is as follows:

1. Pre-wash in cold water at 25°C for 6 minutes
2. Hot-wash in 65°C water for 16 minutes, with detergent added
3. Rinse in 70°C water for 2 minutes
4. Disinfected in 90°C RO water for 1 minute and
5. Dried in 110°C hot air for 10 minutes

The cleanness and dryness of the instrument sets are usually inspected in the clean room before packaging. Different colours and various layers of the packaging not only indicate instrument trays belonging hospitals but also ensure the integrity of the

packages.

Sterilization is the last step in the decontamination procedure. Instruments are exposed to steam at a temperature between 134°C and 137°C, and under a pressure of 320 kPa for 3 minutes.

A monitoring system independent of the control system is used for confirmation of disinfection and sterilization cycles. (Figure 2.4) Sealing tape on the sterilization pack is also an indicator, as brown stripes would present if the sterilization temperature was achieved. (Figure 2.5)

Figure 2.4 Control system (left) and monitor system (right) of a steriliser

Figure 2.5 Bandage difference between before (left) and after (right) sterilisation

2.4.4 Challenges and Future Trends

Although inspection for cleanness and function are recommended in the guidelines, it is not possible to thoroughly check all instruments put through. Meanwhile, visual inspection, even with illumination, cannot effectively judge the

efficacy of decontamination process. More and better care should be taken on patient equipment but healthcare sites in the UK do not have enough resources [68]. The only solution to this without compromising patients' safety is more effective and efficient care, including the reprocessing of surgical instruments. Fewer staff coping with a rising workload would be inevitable.

To achieve a better result in removing organic residues, approaches to keep instruments moist during transportation and effective protein detection after decontamination process are currently under discussion. Single use instruments have replaced some reusable instruments due to competitive pricing and reduce concern about decontamination effectiveness [69], while the whole of life costs is one of the advantages of reusable instruments.

Another approach to effective cleaning is to combine the removal of contaminants with inactivation [70]. Using low-pressure radiofrequency gas-plasma to clean instruments is one of the new technologies. It destroys organic matter such as proteins turning it into gaseous waste such as CO_2, NO_2 and SO_2. However there are still issues to be solved for more efficient use.

Applying Unique Device Identification (UDI) onto all surgical instruments is also suggested as an approach for the hospital's management system in the future. UDI allows each instrument to carry unique information through its service life. Information includes manufacturer's name, product code, batch number and use record . Such information will provide a more accurate traceability to healthcare staff when an Incident is being investigated, by increasing the tracking level from instrument trays to each item.

UDI has already been widely used all over the world, mostly voluntary and user guided within the GS1 system. GS1 is a non-profit, international organization that provides efficient product identification solutions for many different industries, including healthcare, retail, transport and food service. To help these heath boards to achieve individual instrument tracking, now many global suppliers and manufacturers' products contain UDI as standard printed information [71]. The UDI has been officially proposed as a mandatory requirement in the US in 2012 [72] and there's no doubt that it'll be accepted and used more in the future.

Chapter 3 Current Surgical Instrument Environment

Quality concerns over surgical instruments purchased are raised by many. However the guarantee of quality faces the challenge of competitive pricing. Since the quality issue is supported by little evidence, few actions can be taken to improve the situation. There is an urgent need to review the environment surgical instruments currently work in, to inspect the quality of purchased instruments with a consistent standard and ultimately to provide suggestions and to recommend actions for quality improvement.

3.1 Introduction

3.1.1 Health Board Workflow

Taking NHS Tayside as an example, this section explains the typical workflow of a UK hospital, including decontamination, repair and procurement and highlights areas of vulnerability.

Most trays of general instruments are owned by theatre services and are usually stored within the theatres once decontaminated ready for use. During the preparation for surgery, the required instruments are counted and their condition checked. Once an instrument pack is opened, no matter used or not, it must be sent back to CSSD for re-sterilisation. CSSD is usually remote to theatre in a central facility and deliveries are at set times during the day. (Stracathro Hospital is unusual in having a sterilisation facility adjacent.) The delay in getting instruments washed depends on both the surgery finishing time and the delivery time. For a surgery finished after last delivery of the day the instruments would lie waiting overnight.

If anything unusual is noticed, such as failure of sterilisation, contamination, corrosion or function failure, a report should be sent to CSSD along with the pack, declaring the problems. A 2nd fresh pack may need to be opened to replace instruments. Upon receiving the rejected instruments, CSSD staff take action depending on the issues. If it is determined that some instruments require replacement or repair, the whole pack

would be put aside till the problem is solved and it is complete again. CSSD stock some common instruments for quick replacement. Specialised surgical instrument such as endoscopes are sent back to manufacturers for repair while most general surgical tools reported faulty would be sent out to a contracted repair workshop, Uniplex. Although the action required is decided and carried out by Uniplex, no action is taken to claim their responsibility to the tool, such as putting their trade mark on the repaired instrument. As far as I understand, no passivation process is carried out after repairs, either.

Orders for purchase of new instruments are placed though the Procurement e-system where only specification and the price of the products are available, not the supplier's information. This is due to the purchasing policy, corporate governance and good practice of the Procurement. Instruments are delivered directly to CSSD from suppliers. Instruments will then enter the routine decontamination cycle.

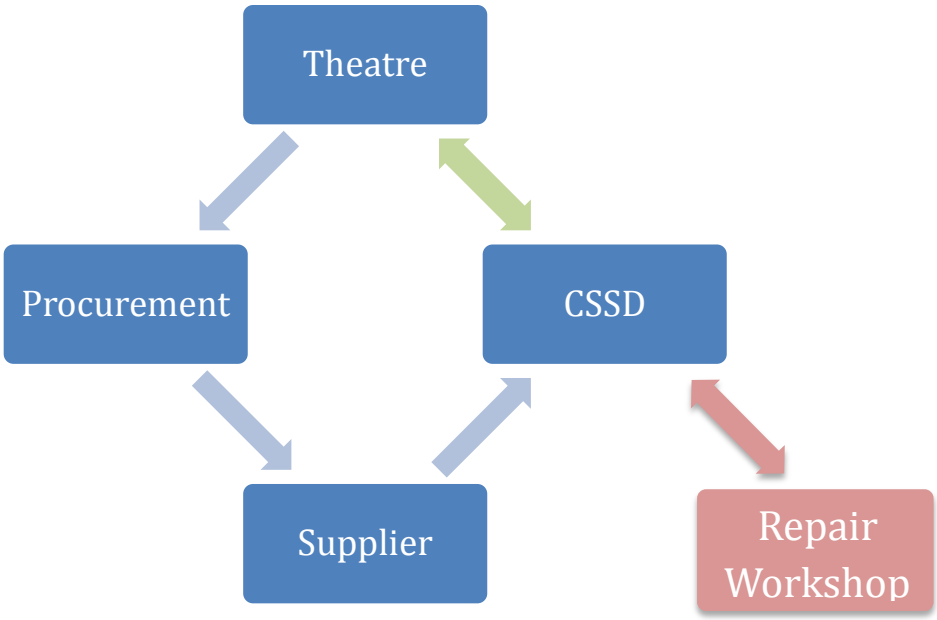


Figure 3.1 Illustration of surgical instrument's workflow

From the workflow described, it can be seen that due to different responsibilities of their roles, each department has their own focus. CSSD cares if the product complies with the decontamination procedure; Theatre staff focus on function; and Procurement pays attention to price. With the suppliers being anonymous in the system, substandard instruments may not be identified until goods are received and perhaps not even then. It is also impossible to avoid further purchase from suppliers who are recognised for supply of substandard products.

Currently, NHS National Procurement is working on a framework that all instruments will be purchased from an approved supplier list. However, the so called "bad suppliers" are now only known to some theatre staff due from experience. There is an urgent need to obtain the evidence nationally, to review suppliers' profile and to analyse reasons of failure.

3.1.2 Overview of the Industry

During this project, contact has been made with many instrument manufacturers and suppliers. Visits have been possible to some manufacturing sites, of both world leading companies and family run businesses. An overview of the industry is given in this section to illustrate the wide range of suppliers. Company names are eliminated to avoid conflicts of commercial interests.

Manufacturers visited are categorised into three levels. The first level is represented by manufacturer A, a world leading surgical instrument company. The second and third level are both family run businesses, with different working scales. The second level is represented by manufacturer B and the third level represented by manufacturer C.

Manufacturer A was is a world-leading company in surgical instrument manufacturing. It has manufacturing sites are all over the world, including Germany, Poland, Malaysia and China. The working scope includes everything from forging to selling. It has its own forge, hence all blanks are made to suit each product and are more readily controlled in-house. Manufacturer A has its own sales representatives all round the world to address customers' problems.

When a batch of blanks is forged, a unique tracing number is assigned to it (received card number). The Certificate of Conformity of the steel is attached and archived under this number. When a job is assigned, the first technician will fill in a job card with a related received card number on it. The job card will be passed on to each relevant technician who will sign and date it until the finished instruments pass the in-house quality control. Then a batch number will be printed on all the instruments within the batch for traceability.

After forging, the remaining manufacturing procedure includes cutting, welding,

fitting, hardening, finishing, passivation, labelling and packaging. However it is usually not a straightforward process but with lots of to and fro between each stage until a satisfactory product is made.

Taking artery forceps as an example. Racks, teeth and the box joint would be cut on forging blanks for initial fitting. While being fitted, every effort is made to ensure that the artery forceps would have straight shanks, meshing teeth, appropriate alignment and a good feel on the racks. A pivot joint would then be finished by drilling aligned holes on both parts of the instrument and hammering stainless steel wire into them. After another check on the fitting, the forceps would be sent for hardening. On return, a technician would inspect all fitting criteria again and make adjustments if needed. Finally, the instrument will be polished, cleaned, passivated, inspected, labelled and packed prior to shipping. A gold plated model is always used (Gold Standard) throughout the process for reference.

Manufacturer B is a surgical instrument manufacturer located in Sheffield, which was once known to the world as the centre of the British steel industry. It has been manufacturing surgical instruments since 1948 and remains one of the few British manufacturers. Compared to manufacturer A, its working scope does not include forging but purchasing forged blanks as a start of their manufacturing process. It does not have a sales department itself either, but promotes their products through another trading company.

Because all forgings are purchased from external companies, forging blanks with the closest length will be used. If the length of the blank were slightly longer, it would be cut into the right length by taking some handle material off. The handle and the working end would then be welded together. After fitting, the forceps would be sent to an external company for hardening.

Manufacturer C is a small family run business located in Sheffield, founded in 1936. Compared to the two companies described above, manufacturer C has the smallest working scale. Most of its products are purchased in a near finished state, wanting only final polishing and labelling. It would only keep the products that meet their requirement, polishing them to give a mirror finish, labelling and packing them before dispatch to customers. Usually, instruments supplied by such manufacturers are not passivated however it cannot be distinguished by visual inspection. In this case,

although the most critical part of the manufacturing procedure (fitting) is actually carried out by another company, manufacturer C still holds the responsibility for the product quality. It is then considered that C is the manufacturer while the other company is their subcontractor.

Although all manufacturers have different skills and specialties, the industry of surgical instruments still works in an apprenticeship manner. New technicians would receive years of training from experienced staff and receive a certificate after all the necessary skills are acquired. It is fair to state that not only the quality, but also the consistency of one company's work, depends on their technicians' skill and experience. It is significant to distinguish the manufacturers who can provide quality assured instruments (such as compliance with ISO 13485) from the ones who cannot.

3.2 Materials and Methods

As mentioned in Chapter 1, Barts and London NHS trust is the only place in the UK who have previously reported an inspection study. Results were categorised into four types: good, pass, poor and fail. Only failed instruments would be rejected while the other three stati indicate quality under a pass condition. Detailed results of the 2004 inspection show that, among 730 rejected instruments, identified flaws include absence of manufacturer's name, machining burrs, debris in teeth, cracks, failure of correct meshing of ratchets, soldering faults, and corrosion [1, 5]. The number of instruments with each reason can be seen in Table 3.1.

Figure 3.2 illustrates the rejection rate reported by year from 2000 to 2015 [73]. It can be seen from the figure that although the rejection rate varies each year, there is a trend of decrease from 2000 to 2015. The overall rejection rate in the 16 years is 11.3% of 51157 instruments, while the rejection of recent five years (2011-2015) is 8.1%. According to Mr. Tom Brophy, this is a result of multiple communications with the suppliers, declaring standards and requirements that comply.

Although the rejection rate of an individual manufacturer can be as high as 35% [3], purchasing from such manufacturers cannot be prevented due to the anonymous purchasing system. There is a definite need for routine inspection of newly purchased surgical instruments.

Surgical Materials Testing Laboratory (SMTL) [74] is another organisation that is known to carry out similar work. It is part of the Welsh NHS, funded by the Welsh Assembly Government and based in Bridgend. The instrument inspection work done by SMTL is generally performed on a commercial basis, thus its result statistics are not available to the public.

Rejection Reason	Number of Instruments
Absent manufacturer's mark	254
Machining burrs in teeth	116
Cracks	91
Failure of correct meshing of ratchets	71
Soldering faults	47
Failure of jaws of needle holders	36
Protruding tissue forceps guide pins	35
Failure of cutting action	34
Corrosion	28
Deficient electrical insulation	10
Sharp burrs on handle grips	8

Table 3.1 Number of rejected instruments categorised by reasons (Adapted from [1])

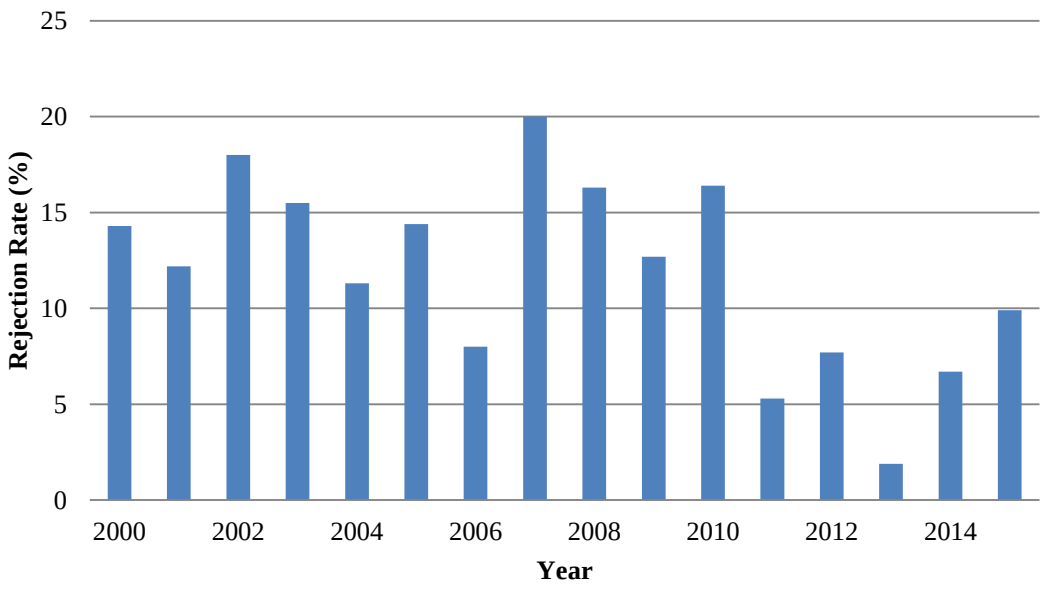


Figure 3.2 Rejection rate Barts and London NHS Trust from 2000 to 2015 [73]

As NHS Procurement in Scotland is currently developing a list of suppliers trusted for quality, I had the opportunity to review their products beforehand. Establishing a list of accredited suppliers would more readily assure the quality of purchased goods, still with a free choice for procurement under the anonymous e-system. To fulfil the need of inspecting purchased surgical instruments equitably and recording the results for future analysis, a test protocol and a database is developed.

3.2.1 Test Protocol Development

As described in section 2.3, the current British Standard related to surgical instruments is BS EN ISO 7153 [42-45]. It consists of 4 parts and was first published in the 1980s. The current revision was published in 2001, dated 15 years ago. Although there exist increasing types of surgical instruments numbering many thousands, the British Standards remain relatively unchanged as shown in Table 2.3.

BS EN ISO 7153 Part 2 – 4 only cover the common instruments, such as artery forceps, needle holders, dissecting forceps and scissors. More specialised and complicated instruments, which usually require more delicate craftwork, are not mentioned in these Standards.

Reviewing BS EN ISO 7153, it is noticeable that the philosophy behind all three parts is very similar. Each part of the standard covers a wide range of requirements, including material, hardness, corrosion resistance, function, surface condition, packaging and marking. However, not all of these specifications are testable on an order by order basis. Firstly, it is impossible to test the material used for a specific instrument without a high cost and the test result may not be reliable as the differences among stainless steels are minimal. Second, the two hardness tests described in ISO standards both leave a dimple on the tested instrument, hence damaging the surface finish. Lastly, testing the corrosion resistance of the instruments is extremely time-consuming. One test using boiling water takes at least 3.5 hours.

Considering the factors above, I decided to develop a test protocol for new instruments, complying with the philosophy of British Standards but also capable of application to more instrument types with tests and that can be performed on a routine basis. Some details of the protocol are explained below and the protocol can been seen in full in Appendix A.

The test protocol consists of two major parts: General Requirements, Function and Specifics. Specifications that can apply to all instruments are detailed in the General Requirements, including markings, material, surface condition, and packaging. Different from the material specifications in the British Standards, this test protocol only requires manufacturer to provide a statement declaring if the material used is suitable for the specific purpose and details if possible.

The Function and Specifics are classified by which category of surgery instruments are used in. This allows easier and quicker locating. Currently, the protocol has 3 categories, General, ENT & Neurosurgical Instruments and Orthopaedic & Plastic Surgery Instruments.

The categorization is then down to instrument types within each section. However, it is noticed that the commonly used category names of surgical instruments are confusing for non-experts. For example, a pair of tissue forceps can be in the shape like artery forceps with box joint and ring handles, as well as be in the shape of dissecting forceps which is formed from two flat pieces of steel welded at one end. It is easily seen that the testing methods for these different tissue forceps would be very different. It depends on the exact instrument name to distinguish which kind of tissue forceps it is, while it is usually named in recognition of a famous doctor, thus the name does not reflect on its function and purpose. To ensure the ease-of-use of the protocol and to avoid as many misunderstandings as possible, a description and a list of example instrument types are written for each category.

The testing methods are mostly derived from the British Standards. Where not covered by the Standards, the testing methods were adapted from commercial test prototcols and industrial practice experiences. One of the commercial products used is Aesculap Technical Service Test Kit (Aesculap: Tuttlingen, Germany) and the other is InterLock Manual (InterLock Medizintechnik GmbH: Lensahn, Germany). A typical example of the adapted testing methods from industry experience is the Allis test. It is a test well known within the industry for tissue forceps with ring handles. To perform an Allis test, lift a piece of printing paper by two corners and clamp tissue forceps upwards on the bottom side. Close the first rack and pull the instrument downwards. Test paper shall not tear apart. This test aims at checking the surface of the serrations as tissue forceps are intended to manipulate tissue without any harm. Full details can again be

seen in Appendix A.

The test protocol was reviewed and approved by the Association of British Healthcare Industries (ABHI). All instruments purchased to Ninewells Hospital during my project were tested against this protocol.

3.2.2 Database Development

A database was developed using Microsoft Access. The database was designed to be user-friendly and hence suitable for routine non-expert use. The database collates information of manufacturers, suppliers and health boards; inspection results and reason for rejections and generates statistical reports.

There are 11 tables in the database, each for a key aspect of information. The use of each table and the relationship between them are described below.

Tbl_Supplier and Tbl_Manufacturer contain the profile information of suppliers and manufacturers. A manufacturer is a company that has its name on the instrument and hence carries the responsibility for the product. Information for manufacturers include company name, country of manufacture, host country of CE mark, whether the manufacturing procedure is subcontracted, traceability of the steel used, information printed on products and contact details. The profile of the staff that carried out the inspection is stored in Tbl_Engineer. Tbl_HealthBoard and Tbl_Department are independent to each other. Tbl_HnD obtains information from Tbl_HealthBoard and Tbl_Department to create corresponding entries.

Unlike the work performed in Barts, the result of instrument inspection is only categorised into two, pass and fail. This is to eliminate the vague boundaries between states within the pass condition.

Forty five Instrument types are used, shown in Table 3.2. In the table, some instruments types appear with different letter postscripts. These letters are added to help in distinguishing the shape of surgical devices. “C” stands for crocodile, indicating the shape of instruments; “B” represents blades, suggesting the instrument is welded from two blades; “R” stands for ring, specifying the shape of instrument handles; and “S/R” specifically refers to self-retaining instruments.

In Tbl_ReasonCategory, 15 reasons of rejection are listed. Each reason has a unique ID number, as shown in Table 3.3.

Types of Instruments		
Air/Battery Tools	Forceps Dressing – B	Raspatories
Alignment	Forceps Dressing – R	Retractors
Box	Forceps Micro	Retractors – S/R
Catheters/Introducers	Forceps Punch/Neuro Rongeurs	Rongeurs
Chisels/Gouges/Osteotomes	Forceps Sponge	Scalpel Handles
Clamps	Forceps Tissue – B	Scalpels/Knives
Curettes	Forceps Tissue – R	Scissors – C
Dilators	Levers	Scissors – R
Dissectors	Mallets	Scissors Micro/Spring
Elevators	Measuring/Jigs	Skin Graft
Endoscope	Mirrors	Snares
Forceps Artery	Needle Holders	Suction Instruments
Forceps Aural – C	Needles	Syringes
Forceps Biopsy – C	Picks/Probes/Hooks	Trocars/Cannulas
Forceps Dissecting	Pliers	Vein Strippers

Table 3.2 Types of instruments regulated in the database

ID	Rejection Reason	ID	Rejection Reason
1	Absent/Invalid Trade Mark	9	Sharp Edges
2	Absent/Invalid CE Mark	10	Bent
3	Function	11	Welding
4	Corrosion	12	Jaw not Mesh
5	Burrs on Jaws/Teeth	13	Differentiation between Parts
6	Crack	14	Imperfect Surface
7	Misalignment	15	Other
8	Guide Pin Protrude		

Table 3.3 Rejection reasons with unique ID numbers

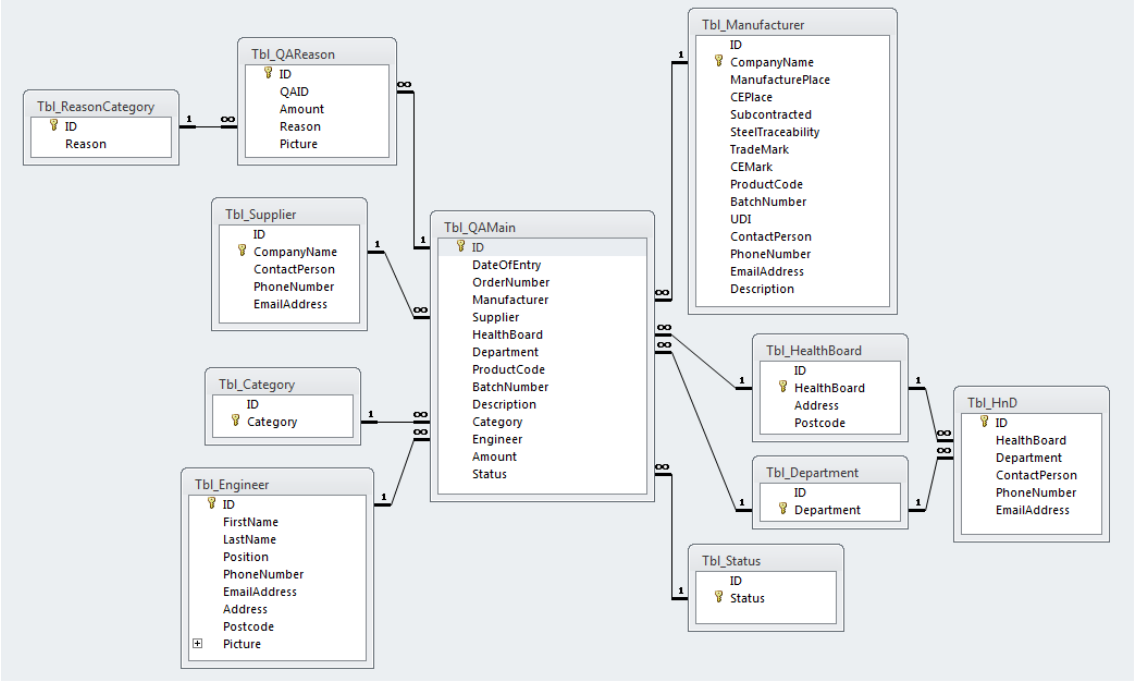


Figure 3.3 Relationship between database tables

Tbl_QAMain and Tbl_QAReason are the two tables used to store investigation results. All information related to the inspected product is archived in Tbl_QAMain, including its date of entry, order number, manufacturer, supplier, the health board and department ordering it, product information, amount and status. If any product is rejected, the reason is stored in Tbl_QAReason.

Figure 3.3 shows the relationship between the tables. Most information required in Tbl_QAMain is linked to the primary key field of the other tables. It is designed in such a manner that users can pick from the related fields, instead of typing. Fields with a primary key symbol will not have identical records. The ID field in Tbl_QAMain is linked to a field named as QAID in Tbl_QAReason. Because QAID is not a primary key field and can have identical records in Tbl_QAReason, it allows each record in Tbl_QAMain to refer to more than one failure reasons. With each rejection reason selected by users, one more record will be generated in Tbl_QAReason, all referring to the same QAID. This design philosophy reduces the workload of users when encountering a batch of identical instruments with multiple faults. The whole batch of instruments would only need to be documented once.

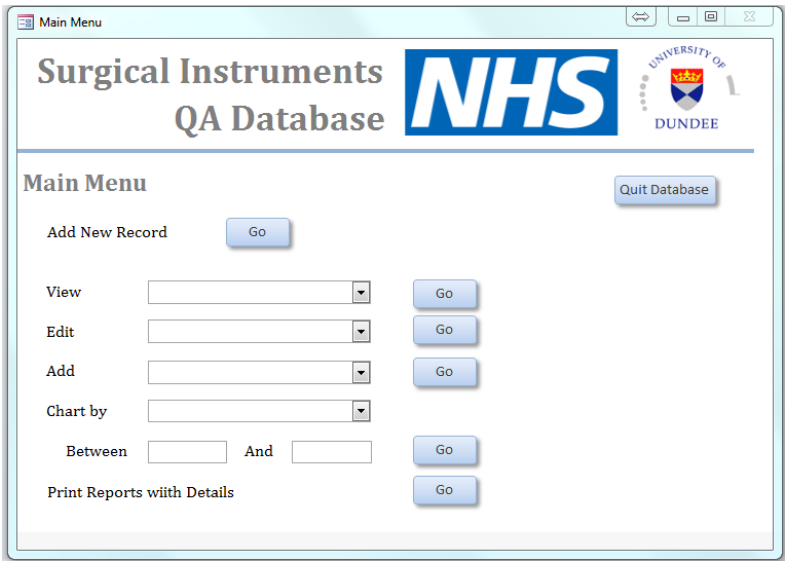


Figure 3.4 Pop up window when database is opened

Figure 3.4 is the pop up window the database is opened. The first and the most important function of this database is to record inspection result of newly purchased instruments. When "Add New Record" is clicked, a new window appears with blank fields (Figure 3.5). All related information can be typed in or selected, including amount of the products passed and failed the inspection. However, the system will only recognise the information already existing in the database. For example, if a category name is typed in, but is not included in the database already, the system will ask users to re-enter a category name. The record will be saved to the background tables when "Save Record" button is clicked. The system will open another window (Figure 3.6) if the status "Fail" is ticked. Details of the reason for rejection can be entered and a relevant image attached. Data is stored in a folder identified by date.

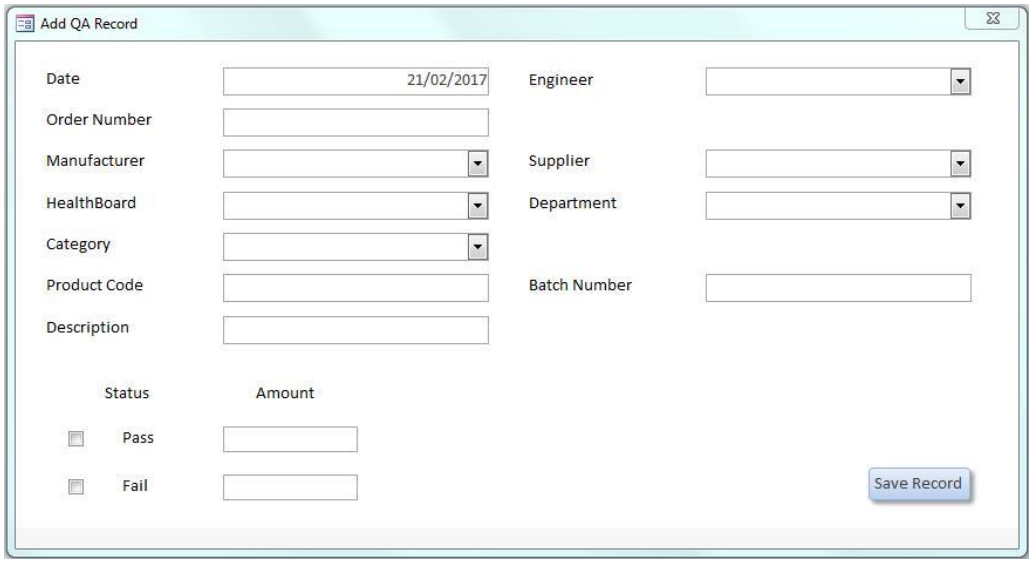


Figure 3.5 Interface of adding new record

As mentioned above, the database design aims at reducing workload by avoiding multiple entries for each batch. In the “Add QA Record” window (Figure 3.5), both “pass” and “fail” can be ticked with individual numbers. The system then automatically generates 2 records in linked tables. For each box ticked in “Failure Reason” window (Figure 3.6), one record would be generated specifically for that reason. The total from “Failure Reason” does not necessarily equal to failed instrument amount from the “Add QA Record” window. This is because there can be multiple reasons for rejection on one instrument.

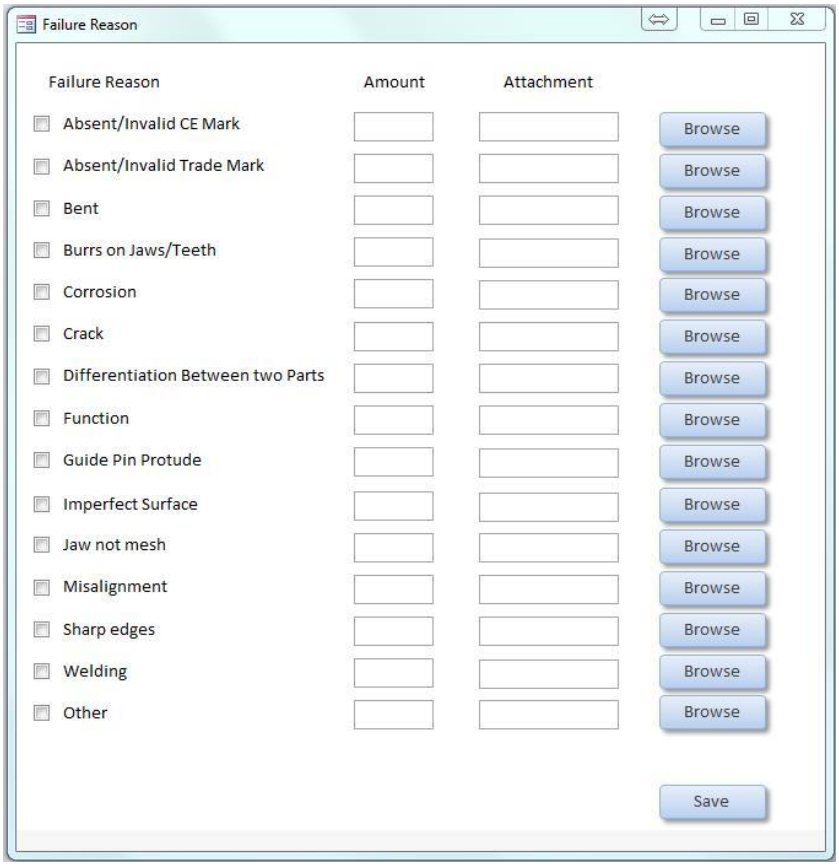


Figure 3.6 Interface of recording failure details

To ensure the database can be generally adopted in different health sites to allow information to be regularly updated and to grant access to recorded information, there are more functions added to the database. Users can “View”, “Edit” and “Add” related profiles, including inspector, manufacturer, supplier, health board and department details. When a new profile of the four mentioned fields is added into the database, a search will be run through all existing records to avoid identical profiles. A message box will pop up to alert the user and the record will not be written.

Statistical results are accessible from the database. A date range can be selected (Figure 3.4), or all results will be shown if the two blocks are left blank. In the combo box of "Chart by", users can choose to view the results by focus of interest. The results can be grouped by health board, department, manufacturer, instrument category and failure reason. Figure 3.8 is an example grouped by failure reason.[1]

A detailed printed report is also available. A filter window (Figure 3.7) pops up after "Print Reports with Details" is selected in Figure 3.4. Similar to statistical charts, date ranges can be either selected or left blank. Other information that can be filtered are health board and manufacturer. If both "HealthBoard" and "Manufacturer" are left blank, all records within the selected data range will be presented. Filters are designed to suit NHS purposes. Information closely related to specific hospitals and manufactures can help in reviewing their situation and communicating with suppliers. An example of a printed report can be seen in Figure 3.9.[1]

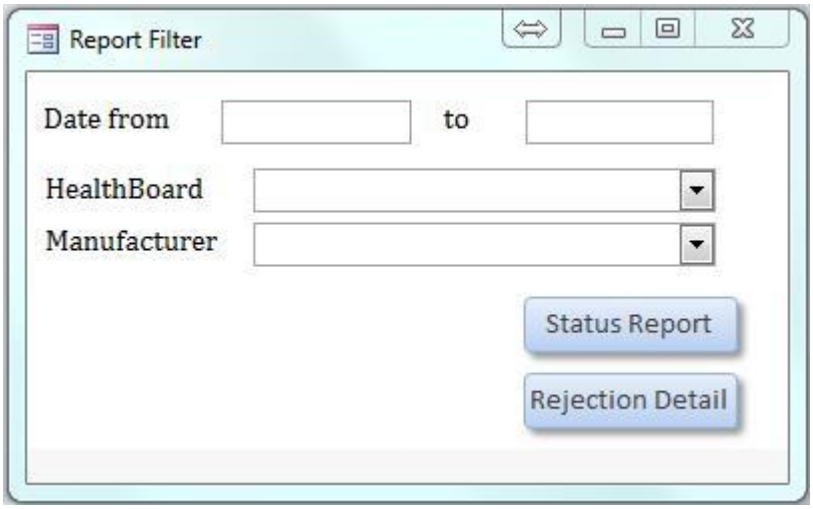


Figure 3.7 Report filter of the database

[1] Data used in the example is just for illustration

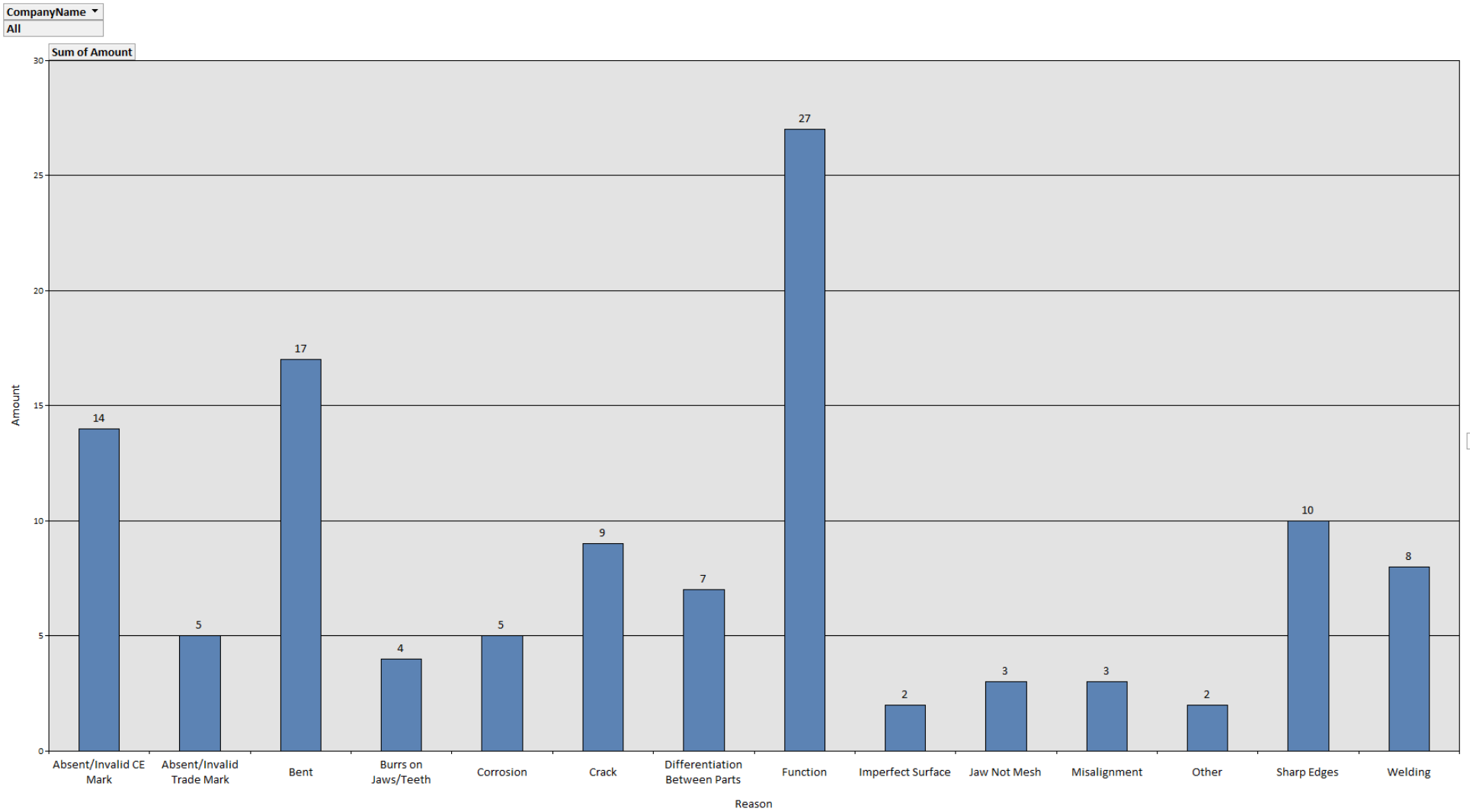
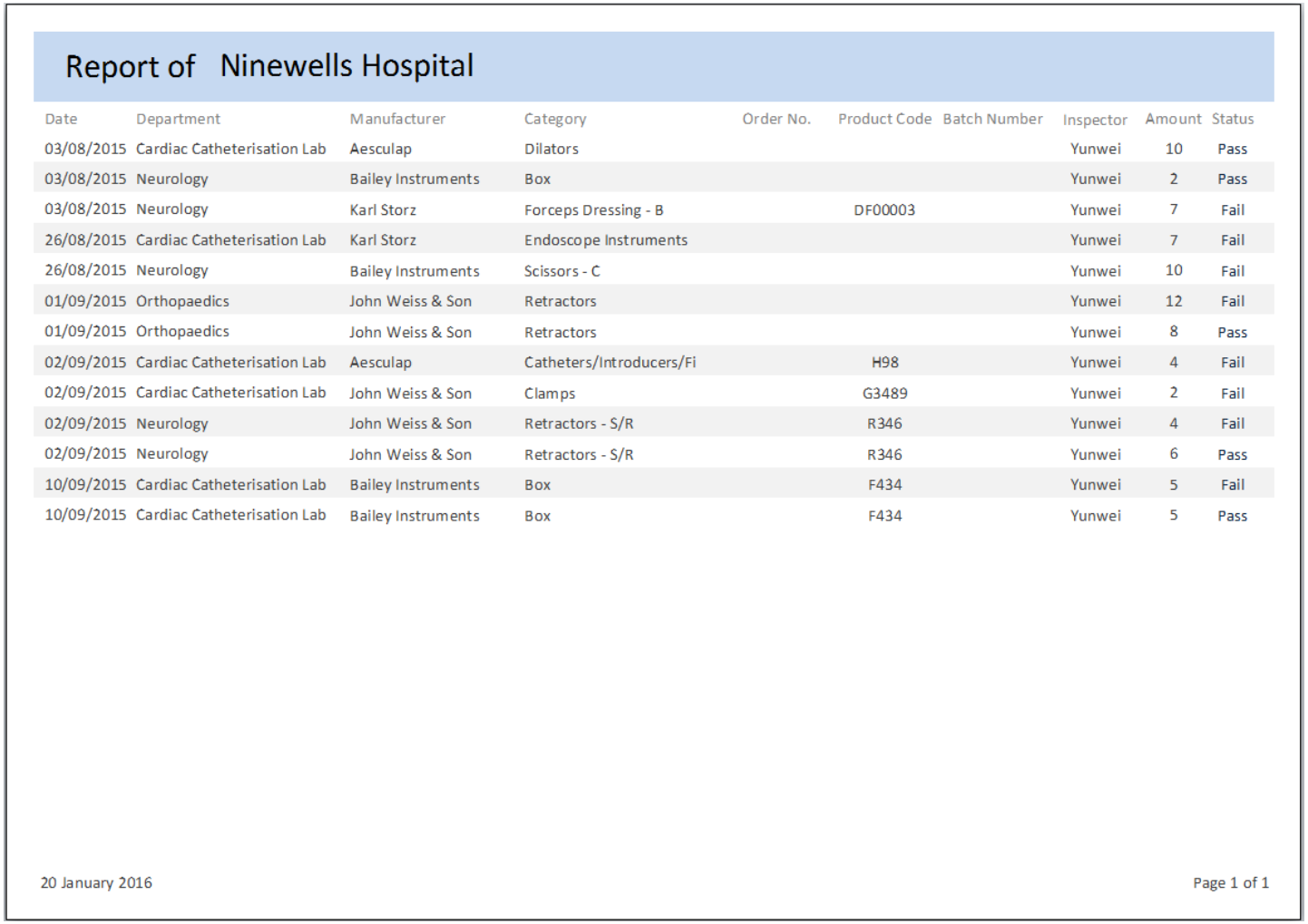


Figure 3.8 Chart by rejection reason



Report of Ninewells Hospital

Date	Department	Manufacturer	Category	Order No.	Product Code	Batch Number	Inspector	Amount	Status
03/08/2015	Cardiac Catheterisation Lab	Aesculap	Dilators				Yunwei	10	Pass
03/08/2015	Neurology	Bailey Instruments	Box				Yunwei	2	Pass
03/08/2015	Neurology	Karl Storz	Forceps Dressing - B		DF00003		Yunwei	7	Fail
26/08/2015	Cardiac Catheterisation Lab	Karl Storz	Endoscope Instruments				Yunwei	7	Fail
26/08/2015	Neurology	Bailey Instruments	Scissors - C				Yunwei	10	Fail
01/09/2015	Orthopaedics	John Weiss & Son	Retractors				Yunwei	12	Fail
01/09/2015	Orthopaedics	John Weiss & Son	Retractors				Yunwei	8	Pass
02/09/2015	Cardiac Catheterisation Lab	Aesculap	Catheters/Introducers/Fi		H98		Yunwei	4	Fail
02/09/2015	Cardiac Catheterisation Lab	John Weiss & Son	Clamps		G3489		Yunwei	2	Fail
02/09/2015	Neurology	John Weiss & Son	Retractors - S/R		R346		Yunwei	4	Fail
02/09/2015	Neurology	John Weiss & Son	Retractors - S/R		R346		Yunwei	6	Pass
10/09/2015	Cardiac Catheterisation Lab	Bailey Instruments	Box		F434		Yunwei	5	Fail
10/09/2015	Cardiac Catheterisation Lab	Bailey Instruments	Box		F434		Yunwei	5	Pass

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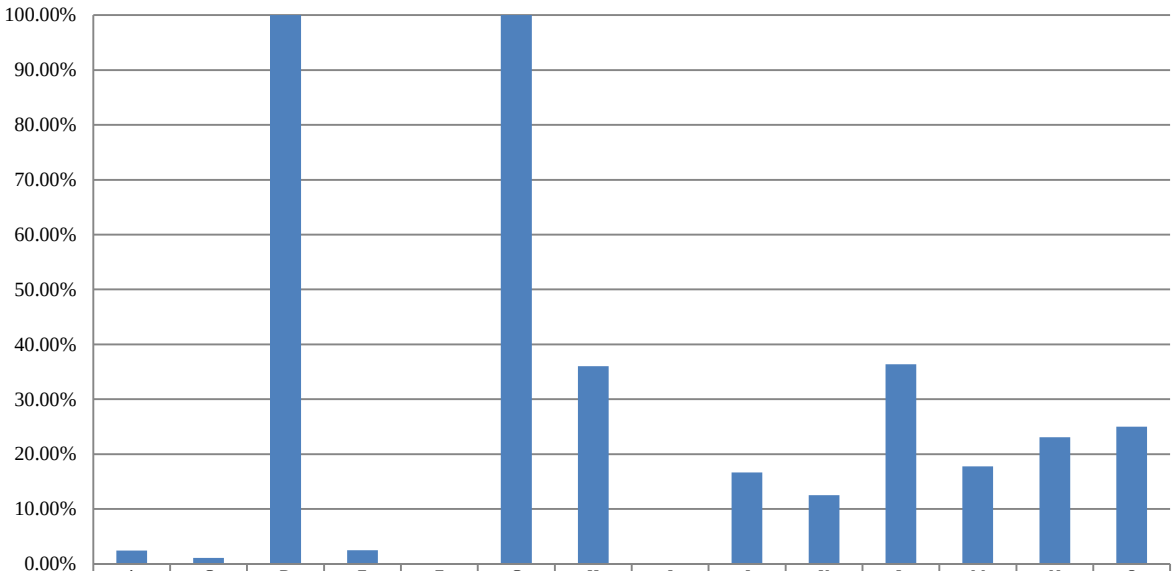
Figure 3.9 Printed report example of selected health board [1]

3.3 Inspection of Purchased Instruments

A total of 801 instruments were inspected, with 143 rejected (a failure rate of 17.85%). Results have been analysed in different ways, including by manufacturer, instrument category and reasons for failure, shown in Table 3.4, Table 3.6 and Table 3.7 respectively.



	A	C	D	E	F	G	H	I	J	K	L	M	N	O
Fail	2.43%	1.10%	100.00%	2.50%	0.00%	100.00%	36.00%	0.00%	16.67%	12.50%	36.36%	17.74%	23.08%	25.00%

Table 3.4 Failure rate by manufacture

From Table 3.4, it can be seen that different manufactures provide instruments with markedly differing ranges of quality. As mentioned previously, the manufacture of surgical instruments is still a craft industry, where the quality and consistency of the products are controlled by hand rather than a programmed machine. This is a major reason for the variable failure rates. Although most manufacturers in the industry have some Quality Control, human error is simply inevitable. Understanding the quality and consistency of the products a manufacturer can supply would significantly reduce the unnecessary involvement with unreliable suppliers.

On the other hand, such a strong relationship between product quality and manufacturers is suspected as a result of their manufacturing level, as described in section 3.1.2. A questionnaire is then sent to all manufacturers listed in Table 3.4 requiring information such as their subcontract and manufacture status. The questionnaire can be seen in Appendix B and information obtained from returned

questionnaire can be seen in Table 3.5. Although not all manufacturers replied, the relationship can be clearly seen. Taking manufacturer A, C, D and H as examples, it can be seen from Table 3.4 that the rejection rates vary greatly. Both D and H have a much higher failure rate (100% and 36%) than average while A and C much lower (2.43% and 1.10%). According to the information gathered, both D and H belong to the third level manufacturers who subcontract the bulk manufacturing work to other companies. On the contrary, A and C are manufacturers of the first and second level who undertake the fitting jobs in house.

Referring to Table 3.6, artery forceps have the highest failure rate among types (42.86%). Others with more than 20% rejected include clamps, dissectors and scissors. The commonality in the 4 types is that they are instruments widely used in most surgeries. With the high market demand, forgings with various sizes and shapes can be produced in large numbers for a fairly low price without as much handcraft needed. Most suppliers can supply these types. However, some of these instruments are for quite delicate functions. For example, artery forceps are crucial in their clamping function to stop bleeding. The jaws should not have any sharp edges and should not wound the artery. Similarly, scissors and dissectors are supposed to deliver a clean cut without tearing the tissue. Such instruments supplied by manufacturers with poor quality control increase the rejection rate markedly. Taking artery forceps as an example, among 63 substandard instruments, nearly half of them (30 pieces) were supplied by only 2 companies – manufacturer D and G. In contrast, instruments with lower failure rates are either more specialised with delicate function (such as punch forceps and micro scissors) or general instruments with minimal function requirements (such as mirrors and sponge forceps).

Manufacturer	Supplier	Manufacturing Country	CE Mark Place	Subcontractor	Steel Traceability	Surface Finish	Inspection Rate	Information on Instruments	BS
A	N/A	UK, Germany, Malaysia, Poland	Germany, UK	N/A	Y	Electropolish, Matt	–	Trade, CE, UDI, LOT, Product code	Y
C	Y	UK	UK	N/A	Y	Polish, Matt	100%	Trade, CE, LOT, Product code	Y
D	N/A	Subcontracted	Pakistan	Pakistan	Y	Polish, Matt	100%	CE, Product code	Y
H	N/A	Subcontracted	UK	UK	–	–	–	–	–
I	N/A	UK	UK	N/A	Y	Matt	100%	–	Y
J	N/A	Subcontracted	Pakistan	Pakistan	Y	–	–	–	–
O	Y	Sweden	Sweden	N/A	Y	–	–	–	–
P	N/A	Subcontracted	Pakistan	Pakistan	Y	–	100%	–	Y
Q	N/A	UK	UK	–	Y	–	100%	–	–
R	N/A	UK	UK	N/A	Y	Polish, Satin, Matt	–	–	Y
S	N/A	Subcontracted	UK	–	Y	–	–	All on packaging	–

Table 3.5 Information obtained from returned questionnaire[2]

[2] "–" refers to the absence of relative information

Instrument Type	Pass	Fail	Sum	%
Alignment	3	0	3	0.00%
Box	5	1	6	16.67%
Chisels/Gouges/Osteotomes	12	3	15	20.00%
Clamps	8	5	13	38.46%
Curettes	5	0	5	0.00%
Dissectors	13	7	20	35.00%
Elevators	20	0	20	0.00%
Endoscope	1	0	1	0.00%
Forceps Artery	84	63	147	42.86%
Forceps Aural-C	4	1	5	20.00%
Forceps Dissecting	99	6	105	5.71%
Forceps Dressing-R	20	0	20	0.00%
Forceps Punch/Neuro Rongeurs	2	0	2	0.00%
Forceps Sponge	4	0	4	0.00%
Forceps Tissue-B	8	0	8	0.00%
Forceps Tissue-R	24	2	26	7.69%
Measuring/Jigs	8	2	10	20.00%
Mirrors	10	0	10	0.00%
Needle Holders	35	5	40	12.50%
Other	20	0	20	0.00%
Picks/Probes/Hooks	5	0	5	0.00%
Retractors	178	31	209	14.83%
Retractors-S/R	11	0	11	0.00%
Rongeurs	3	0	3	0.00%
Scissors-R	67	20	87	22.99%
Scissors Micro/Spring	6	0	6	0.00%

Table 3.6 Failure rate by instrument type

The two factors described above are considered to be the result of the self-declaration of surgical instruments. As mentioned, surgical instruments are categorised as Class I due to their short contact time with patients. To allow legal trading of Class I devices in the European Union, a CE mark must be affixed to the

product by declaring the product's conformity with related *Essential Requirements*. However, the conformity assessment can be completed by simply a written statement from the manufacturer. For devices without a measuring function and supplied in non-sterile condition, no approved Notified Body need to be involved [75]. As a result, any surgical instrument supplier can declare their products conformity regardless of the product quality.

In Table 3.7, "Absent/Invalid Trade Mark" and "Absent/Invalid CE Mark" are responsible for a large proportion (21.7%) of failures, although these are fundamental requirements for commercial products. Function is another major rejection reason, including scissors' cutting ability and artery forceps' and needle holders' clamping ability. Other reasons, such as burrs on jaws, misalignment and jaw not mesh are seen on instruments with a biting function and instruments composed of two parts, such as artery forceps. Although Brophy received 28 corroded products and raised it as a concern, corrosion does not appear to be a problem for Ninewells Hospital in newly purchased reusable instruments.

Rejection Reason	Amount	Rejection Reason	Amount
Absent/Invalid Trade Mark	22	Sharp Edges	13
Absent/Invalid CE Mark	56	Bent	20
Function	53	Welding	2
Corrosion	1	Jaw not Mesh	23
Burrs on Jaws/Teeth	53	Differentiation between Parts	30
Crack	5	Imperfect Surface	42
Misalignment	30	Other	5
Guide Pin Protrude	5		

Table 3.7 Surgical instruments' failure rate by rejection reason

3.4 Inspection of Instrument Design

There is concern regarding the conventional box joint (Figure 3.10) of surgical instruments. These are seen on hinged general instruments, such as scissors, artery forceps, clamps and needle holders. The box joint is a hidden trap for organic debris thus making cleaning difficult and thus making sterility uncertain. A surgical instrument manufacturer developed a new design to solve the current decontamination issue.

Figure 3.10 Example of a conventional box joint

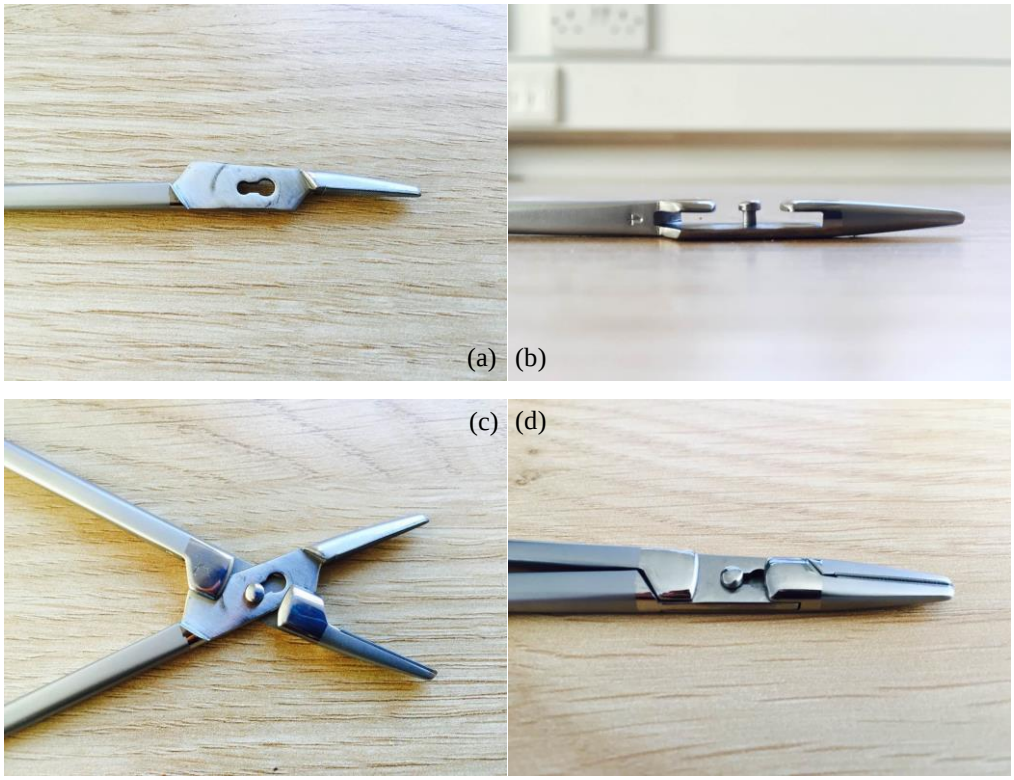


Figure 3.11 Images of the inspected needle holders
(a) Male part; (b) Female part; (c) Top view of open box joint; (d) Top view of closed joint

The manufacturer developed a prototype of a needle holder without a conventional box joint which allows the blades to be dismantled for cleaning. (Figure 3.11) The newly designed dismountable needle holder has not yet placed in manufacturing to date. The needle holder was inspected to validate if the instrument is fit for purpose. The inspection was carried out visually and the function tests were performed according to related British Standards and developed protocols.

The male part of the dismountable joint has two holes instead of one in the traditional design, as shown in Figure 3.11 (a). The two holes have different diameters

and are connected through a narrow channel. The smaller hole is located in the centre of the joint and works as fixed location for its counterpart.

The female part of the dismountable joint (Figure 3.11 (b)) has one side cut open for counterpart insertion and the other side same as the traditional design. A bolt-shaped hinge is welded onto the female part.

On assembly, one needs to insert the hinge into the male part's big hole, with an angle of approximately 90° so the male part can sit on the bottom of the female part. By sliding the male part of the needle holder, the hinge is located in the small hole, as illustrated in Figure 3.11 (c). The instrument can then be operated as traditional ones.

To illustrate Sinton's consideration on the effect of surface finishes on instrument's corrosion resistance, the surface of the needle holder is finished differently from other commercial products available on the market. The newly designed joint is mirror-polished as, according to the manufacturer, the mirror polish is believed to have a lesser adherence to contaminants such as blood. The remaining part of the needle holder is matt finished due to its vast popularity among surgeons.

A 0.2mm diameter plastic wire is used to test the clamping function of the needle holder. Closing on all three racks, the test material remained immovable. The instrument showed good ability in clamping and there was no evidence of working end catching. There is also no gap observed between tungsten carbide inserts and the instrument body.

It can be seen that although the needle holder prototype is equipped with a new joint design, the function is not compromised. Besides, the new design of the joint allows a full disassemble prior to decontamination process and would eliminate the possibility of organic debris being trapped.

However, the manufacturing of surgical instruments still relies on craft work instead of auto machining. Hence, the major concern in such design is the possibility of a miss match of the components, when multiple pairs present, which might lead to less than perfect function. There is also cost of manufacture to consider

The instrument prototype does not bear any marking because it is a prototype, not a commercial product.

In summary, the instrument passed all tests and is fit for purpose. Detailed

examination and testing of the prototype raised no clinical concern. However, it is recommended to look for a solution to avoid the possibility of miss matches prior to applying the new design to more instrument types, such as artery forceps and scissors.

3.5 Conclusion

The local failure rate of newly purchased surgical instruments aligns with overall rates reported elsewhere. A strong relationship is found between the rejection rate and manufacturers as well as instrument types. Although rejection reasons of Ninewells Hospital are not identical with findings from Barts, it can still be concluded that there is an urgent need for regular inspection of surgical instruments purchased.

From the inspection of the newly designed needle holder, it can be concluded that new designs of surgical instruments aiming at solving conventional problems may introduce new concerns. Although new designs of instruments are very much encouraged, the main focus should still be put on keeping instruments remain fit for purpose in the clinical environment.

Chapter 4 Investigation of Incidents and Failures

Whilst it is important that substandard instruments are rejected on delivery instruments can fail or be found to be faulty in use. This may be because of poor design, poor manufacture (including inappropriate material), misuse or damage during use or cleaning.

Such Incidents should be investigated by CSSD and escalated to the IRIC as appropriate although it is widely accepted there is very significant under reporting. During this work, with the co-operation and help of IRIC, Dr Sulisti Holmes of HFS, CSSD, Ninewells and others every opportunity was taken to investigate instrument failures. Numbers mean this can by no means be considered a survey but provides examples and an indication of the types of problems that are required to be addressed.

4.1 Introduction

IRIC and MHRA are responsible for Incident recording in Scotland and England respectively and issuing Safety Action Notices accordingly.

There are two methods of becoming aware of an Incident. One is through the manufacturer, when a batch of product is identified to with a common problem and a recall is required. In this case, the manufacturer issues a Field Safety Notice (FSN) and it is the company responsibility to alert all customers. They would also inform MHRA directly and FSNs are available on a central website [76]. NHS staff are also obliged to report Incidents through Datix [77]. These may be dealt with internally or escalated to IRIC/MHRA.

An adverse Incident [78, 79] is defined as “an event that causes, or has the potential to cause, unexpected or unwanted effects involving the health and safety of patients, users or others”, according to HFS. “Near misses” are just as much Incidents as they cause safety concerns and analysis can help to prevent further adverse Incidents.

The causes of Incidents include but not limited to manufacturing defects, material degradation, incorrect use, inadequate maintenance, damaged packaging, unsuitable

storage and inappropriate cleaning methods.

If an Incident reported to IRIC or MHRA by NHS staff or supplier is deemed serious enough, a Safety Action Notice is cascaded out to all Health Authorities. They are obliged to acknowledge and act upon it accordingly.

This system is part of the post market surveillance for the Medical Devices Directive and it is designed to make all users aware of product flaws and issues. The Risk of a recurrence should be eliminated or managed to reduce it not only to acceptable levels but as low as possible.

There is generally accepted to be under reporting of Incidents. This is due to misunderstanding of the definition, confusion as to who is taking responsibility to report, workload on staff. It is made worse for surgical instruments because they are perceived as secondary to major medical equipment and the general practice for faulty instruments, rusty, contaminated or non-functional to be reported by an exclusively internal system to CSSD.

All this makes meaningful statistical analysis of instrument failure very difficult. Under reporting and statistically small numbers are compounded by variations in description of instruments, confusion over manufacturer and supplier and lack of detail of failure.

Even with these limitations there were still 62 Incidents documented by IRIC from 2009 to 2013 [7]. Incidents included corrosion after short-term service, fractures and failure to function correctly. Two Incidents left instrument fragments in the patient requiring further surgery for retrieval.

From January 2008 to May 2010, NHS Tayside had “eight objects, including the tip of a guide wire and the tip of a needle, were left inside patients during surgery”, according to BBC news [8]. Luckily, none of the patients was injured due to these Incidents. Interestingly no records can be found of formal reporting of these Incidents on IRIC or MHRA system.

Instrument failure can be caused in surgical procedures by several major reasons – poor manufacture, use of inappropriate material, poor design or inappropriate use or by aggressive cleaning protocols.

Analysis of these Incidents, should better inform us of the general quality of surgical instruments and in the long term, it will help in the Quality Assurance in the Supply Chain, improving reprocessing and product design.

During this project, many hospitals and manufacturers came to me with different requests. Most relate to instruments failure or corrosion and some relate to the design of new products. For each case studied, possible causes were identified and suggestions given where appropriate for improvement. Some examples are discussed in this section. Detailed reports were written of all cases and submitted to customers.

For the sake of confidentiality, names of hospitals involved are not mentioned in this thesis. A number of specific cases of failure were investigated. In some cases this was at the request of the Authority as part of the investigative procedure. They are presented here to give examples of failures and how they may be prevented.

4.2 Investigation Methods

Several tests were performed to understand the possible root causes of instruments failure. They include:

1. Visual inspection

Visual inspection is usually the first step in the whole investigative process. By studying the area of interest under up to 70x magnification with good illumination, much information can be gleaned such as corrosion pitting, rust deposits and surface texture. A CCD camera was used to record images.

2. SEM imaging

Imaging by using Scanning Electron Microscope (SEM) reveals still more information since a much higher resolution can be reached. Instead of light, secondary electrons ejected from the sample surface by an X-ray beam of 5-15kV are detected to form the image. The sample chamber is held under vacuum during the experiment to prevent scattering of the electrons.

3. EDS analysis

Energy Dispersive Spectroscopy (EDS) is an analytical technique embedded in

the SEM. It usually uses an X-ray beam of higher energy than SEM imaging: 20kV. The number and energy of the electrons emitted are then measured. In this work, EDS is used to measure and analyse the chemical composition of samples.

4. XRD analysis

X-ray Diffraction (XRD) is also an analytical technique used for chemical composition analysis. Crystalline structured composition can be detected since each unique crystal structure results in a characteristic diffraction pattern. It is used in this experiment as an additional method, to confirm the results for some elements detected by EDS.

4.3 Analysis of Reported Incidents

4.3.1 Case Study – A

Two trays of dental instruments were investigated because brown stains were found on the Flexichange periodontal curettes. The concern was primarily whether the stains were blood due to inadequate decontamination or corrosion.

Tests carried out include visual inspection, SEM imaging and EDS analysis. In addition, curette tips with brown stains were immersed into hand wash detergent as used in CSSD, Serquat Instrument Cleaner Concentrate (Serchem: Telford, UK), for 30 minutes to identify if the brown stains were blood.

4.3.1.1 Results and Discussion

Visual inspection showed identified brown staining on both the tips of several instruments and underneath a removable rubber ring (Figure 4.1) on one particular curette. The space between rubber ring and the curette can be treated as a micro-environment as the free flow of liquid is obstructed by the rubber ring. Hence it provides a seat for contaminants as well as it increases the difficulty of decontamination.

Brown stains were found on the two tested curette tips and clear pitting was noticed. (Figure 4.2) After 20-minutes immersion into Serquat Instrument Cleaner Concentrate, all the stains still remain with their original colour and could not be

washed off.

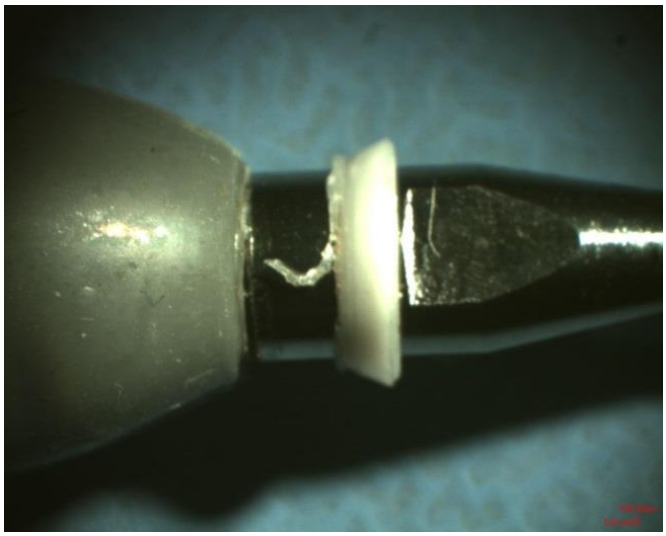


Figure 4.1 Removable rubber ring on dental curette (10x)

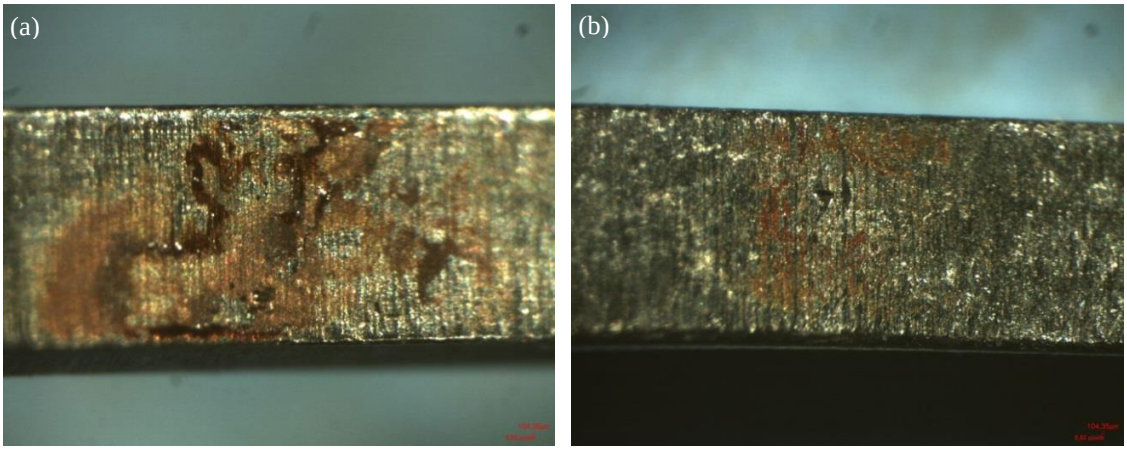


Figure 4.2 Brown stains and pits observed on tested samples (60x); (a) brown stains; (b) pits.

EDS results of unstained areas (Figure 4.3) showed chemical elements including Iron (Fe), Chromium (Cr), Silicon (Si), Oxygen (O) and Carbon (C). The average quantitative result showed a Cr level of 12.36 ± 0.69% by weight. Despite significant appearance differences of brown stains from spot to spot, including collapsed material and corrosion deposits on the surface (Figure 4.4), EDS results from all stained areas were similar, with additional elements such as Phosphorus (P), Calcium (Ca), Sulphur (S) and a comparatively higher level of Oxygen compared to corresponding unstained areas.

The result of the immersion test indicates that the brown stain is not organic residue and the SEM images reinforce that conclusion. In these, the brown stains have a regular geometric shape with clear boundaries. Images can be taken at high

magnifications to reveal crystal shapes due to the good conductivity of samples. Any form of organic residue would have a poor conductivity and images of organic residue under high magnification would reveal very little detail.

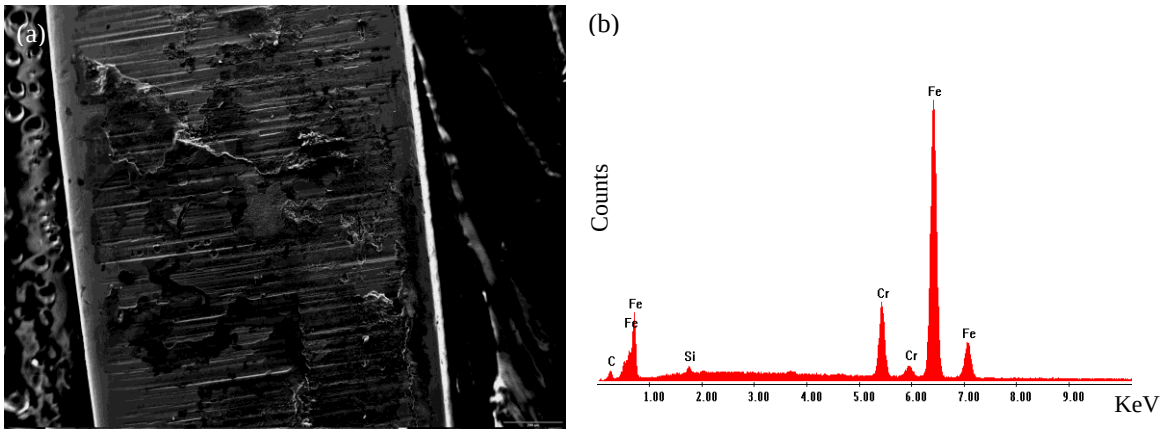


Figure 4.3 SEM & EDS results of unstained area; (a) SEM imaging; (b) EDS result

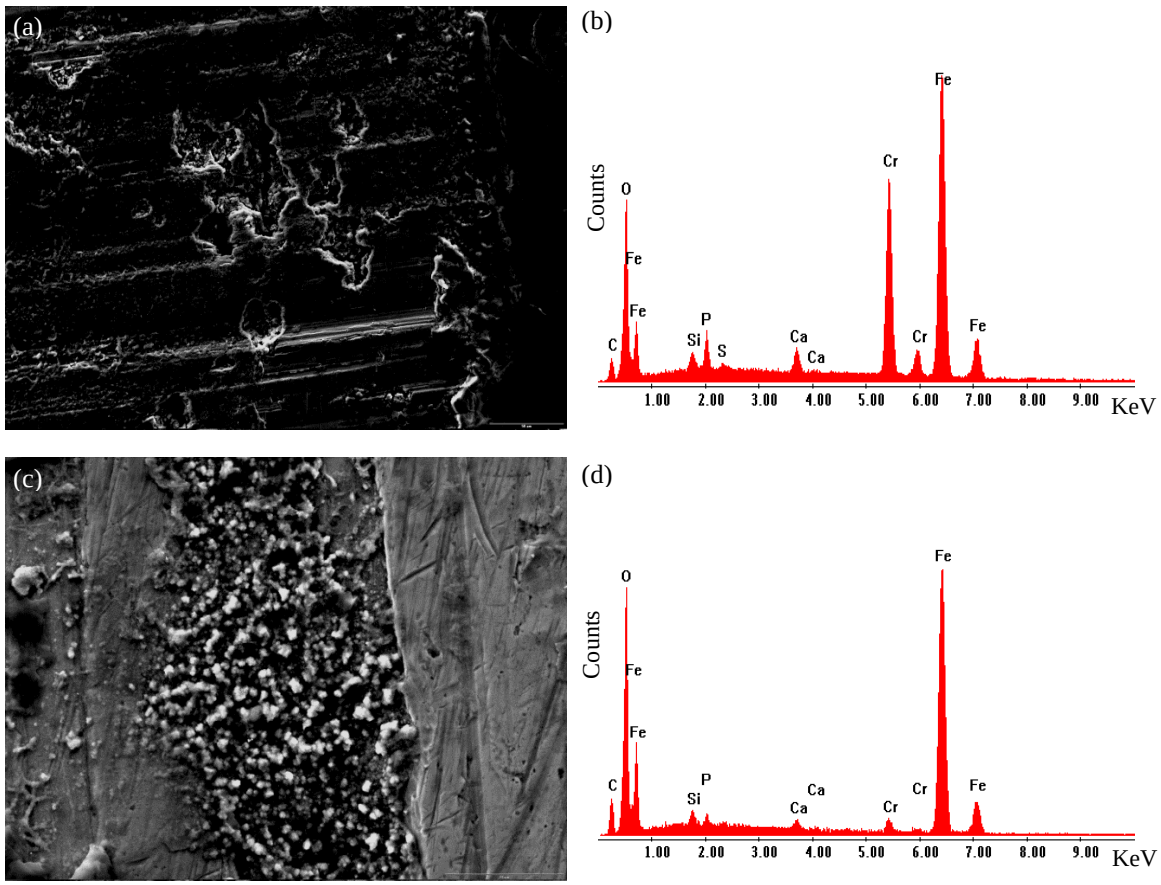


Figure 4.4 SEM & EDS results of two stained areas; (a) & (c) SEM imaging; (b) & (d) EDS results

According to BS ISO 7153-1 [42], Stainless steel Type C and Type D can be used to manufacture dental curettes. The two materials are very similar, consisting of 12% - 14% Cr by weight and small amount (under 1% by weight) of other elements such as Si, S, P, Manganese (Mn) and C, with the remainder being Fe. EDS analysis is very

accurate when the sample is flat and has good conductivity; however it has limitations when identifying elements under 1% by weight, especially quantitatively. It may also leave some elements with small quantities out due to misinterpreting small peaks as background noises. Small concentrations of an element does not however have a significant effect on a material's corrosion resistance. Therefore only Cr content is used to decide if the material is fit for purpose in this respect. Referring to Table 4.1 it can be concluded that the material used for sample curettes at 12.36% is indeed fit for purpose.

Weight (%)	**C**	**P**	**S**	**Si**	**Cr**	**Mn**
Type C	0.26-0.35	0.04	0.03	1	12-14	1
Type D	0.42-0.50	0.04	0.03	1	12.5-14.5	1
Unstained area	-	-	-	0.73	12.36	-

Table 4.1 Chemical composition of Type C, Type D [42] and unstained area

Comparing results of stained areas with unstained areas, there is an increased level of Oxygen detected and one unexpected element, Ca. However, traces of Ca can be easily picked up from water and do not indicate the reason for pitting corrosion. Corrosion is a result of various factors and is usually incremental. In this situation, no particular reason can be identified thus the environment encountered is discussed.

Commonly blood on instruments is not wiped off after use because of the Risk from sharps, and there is a delay of hours before instruments are sent to CSSD for decontamination. Blood, containing a high level of ions, left on stainless steel attacks the passivation layer and initiates corrosion. Once a pit appears, a microenvironment can be easily formed where the pit acts as an anode and the passive layer acts as the cathode. [80]

4.3.1.2 Conclusion

No concern was raised regarding the chemical composition of the material. No manufacturing fault is apparent. It is suggested that shortening the delay time before decontamination or keeping instruments moist may reduce the risk of corrosion. The rubber ring of the curette could be disposed if it serves no function.

4.3.2 Case Study – B

Two trays of instruments for Caesarean Section were reported faulty due to significant corrosion deposits and surface pitting. Additionally, one pair of artery forceps had broken. The instruments involved were purchased in October 2013 and had been in use for no more than seven months.

Two pairs of needle holders with corrosion in the box joints were cut to expose areas of interest and the broken pair of artery forceps was cut to fit into the SEM chamber. Tests carried out include visual inspection, SEM imaging, EDS and XRD analysis. Instruments with brown stains were steeped in Serquat Instrument Cleaner Concentrate for 30 minutes to differentiate corrosion products and organic residue.

4.3.2.1 Results and Discussion

Two trays of caesarean section instruments, four pairs of needle holders and one pair of artery forceps (broken) were investigated. Each tray contains 41 instruments including scissors, forceps, needle holders and retractors. A summary of the instruments' details and conditions can be seen in Table 4.2. Sample images of stains are shown in Figure 4.5.

Most instruments were discoloured while 32 out of 87 (37%) showed evidence of brown staining. All stains remained immovable after 30 minutes immersion in detergent. The immersion test result indicates that the brown stain was not organic residue. Images taken by SEM reinforced the conclusion, as seen in Figure 4.6 (a). In SEM images, the brown stains have a regular geometric shape with clear boundaries. Images can be taken at high magnifications to reveal crystal shapes due to sample's good conductivity. Images of organic residue under high magnification reveal very little detail.

According to British Standard ISO 7153-1 [42], Stainless steel Type B can be used to manufacture needle holders. This contains 12% - 14% Cr by weight and a small amount (under 1% by weight) of other elements such as Si, S, P, Mn and C.

Amount	Manufacturer	Product Description	Tray No.1	Tray No.2
1	R	Tray	-	-
1	R	Dayen Retractor	-	-
6	R	Green-Armytage Haemostasis Forceps	2x pits	2x pits
4	R	Littlewood Tissue Forceps	-	-
2	R	Lane Tissue Forceps	-	-
1	R	Wrigley Obstetric Forceps	-	1x pits
2	R	Surgical Scalpel Handle	-	-
2	R	Bonney Dissecting Forceps	1x pits	1x pits
1	R	Bonney Dissecting Forceps Serrated	-	-
3	R	Rampley Sponge Holding Forceps	1x pits, 1x joint	1x screw
2	R	Mayo-Hegar Needle Holder with TC	2x pits	2x pits
2	R	Mayo Supercut Scissor Curved	2x handle	2x blade
2	R	Mayo Stellite Padded Scissor Straight	2x handle	1x pits
6	R	Spencer Wells STR Forceps Artery	1x joint	2x pits
6	R	Spencer Wells STR Forceps Artery	1x joint, 1x jaw, 1x screw	3x joint

Table 4.2 Summary of instruments investigated[3]

[3] "pits" refers to pitting corrosion noticed in various locations; "handle", "joint", "jaw" and "screw" refer to locations of brown stain

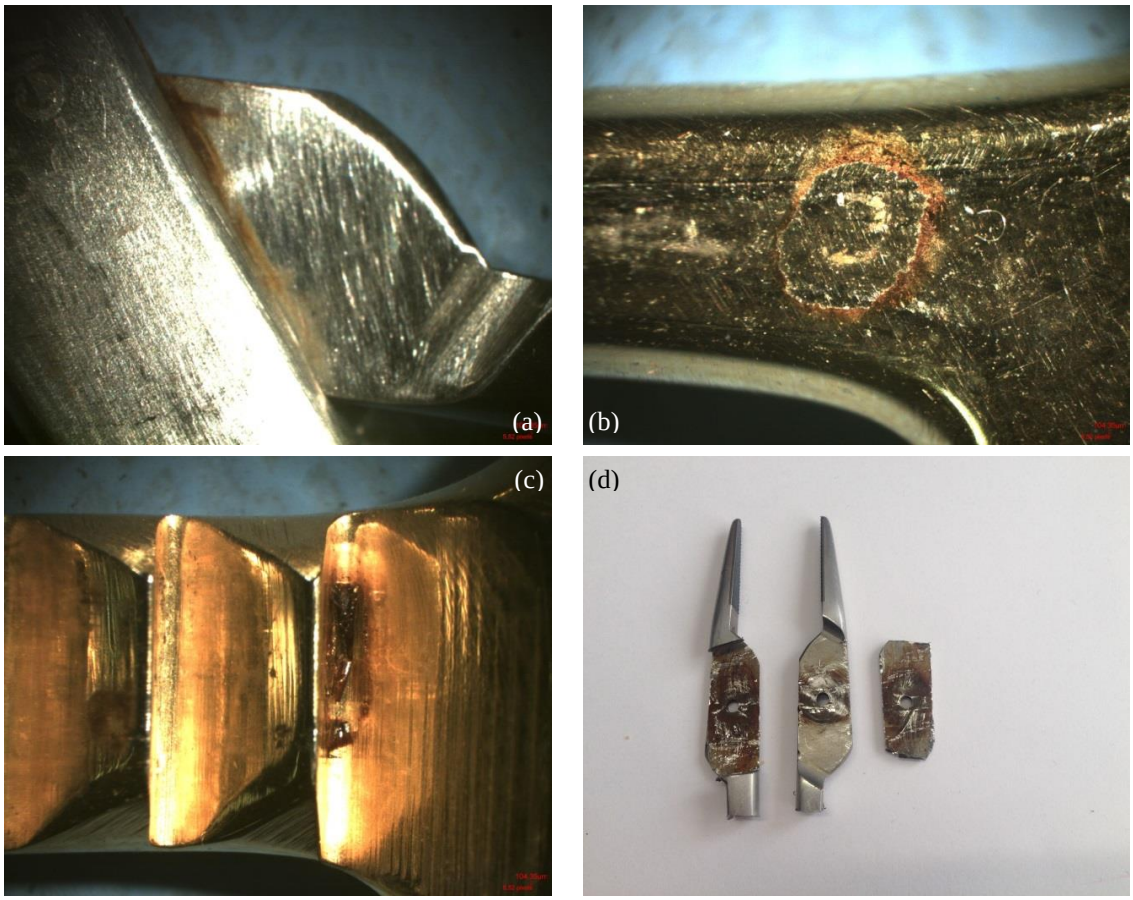


Figure 4.5 Stains on sample instruments at various locations.
(a) box joint (10x); (b) handle (10x); (c) ratchets (10x); (d) incised needle holder

A comparison between stainless steel Type B [42] and the tested samples is shown in Table 4.3. EDS results revealed the chemical compositions of the base materials of the tested needle holders and the broken artery forceps. Interestingly, identified elements in the needle holder include Fe, Cr, Al, Si, O and C and the quantitative result showed 12.52% of Cr and 0.81% of Al by weight. XRD confirmed the appearance of crystallised Al compounds in the needle holders (Figure 4.6 (c)). This implies that the material used is not compliant with relevant British Standards as stainless steel Type B does not have Al as a constituent element. Putting Fe and Al in contact creates a microenvironment with a potential difference between the two elements, has the possibility of causing corrosion. After a pit is formed, being exposed to aggressive environments such as blood will speed up the corrosion. Moreover, comparing results of stained areas with unstained areas, another unexpected element detected is Ca. However, traces of Ca can be easily picked up from water and thus do not indicate the reason of pitting corrosion.

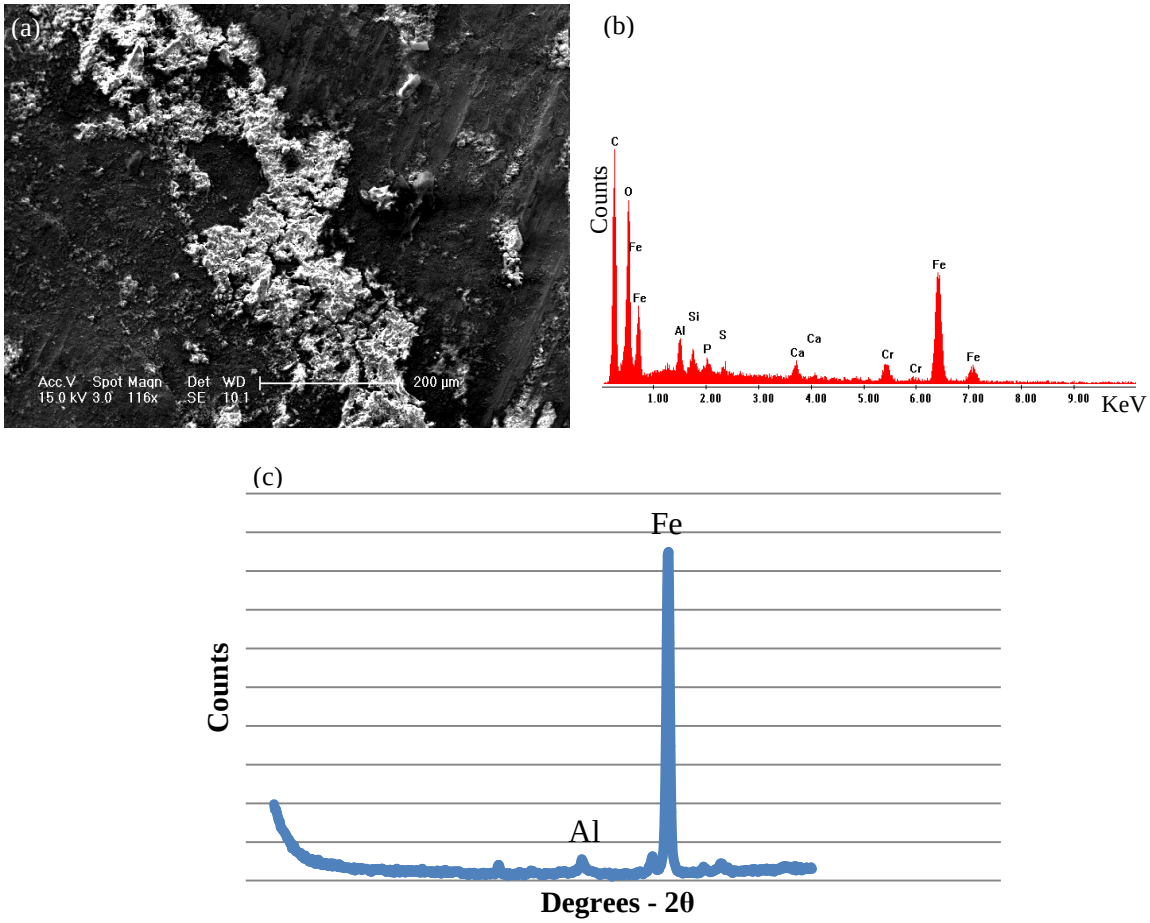


Figure 4.6 Chemical elements detected in needle holder's stained areas;(a) SEM image of a stain; (b) element detected in area (a); (c) Fe and Al crystals detected by XRD

Weight (%)	C	P	S	Si	Cr	Mn	Al
Type B	0.16-0.25	0.04	0.03	1	12-14	1	-
Needle holders	-	-	-	1.17	12.52	-	0.81
Artery forceps	-	-	-	0.88	12.63	-	-

Table 4.3 Chemical compositions of Type B [42] and the needle holder's unstained area

Corrosion products were also found in some box joints where component alignment makes the clearance for cleaning poor at extremities. Organic residue trapped would be hard to wash out. It is important to point out here that the tightness is not a design/manufacture fault since it is necessary for functionality.

Corrosion deposits located elsewhere such as handles may be transferred from other instruments since all are in the same tray. Although instruments made from different materials and have slight potential differences, it will not cause any problems under normal conditions because the influences of other factors are much significant, such as using aggressive solutions. However, if any rust is formed, risk of

cross-contamination will be increased.

Most instruments suffered from discoloration. This may result from inadequate drying or Ca ions from the cleaning procedure. Discoloration should not be taken as a serious problem because it is a thin oxide layer adhering to the base material and will not cause further problems.

As seen in Table 4.3, the EDS result for the artery forceps showed 12.63% of Cr by weight, which fits into the allowed range of stainless steel Type B. It can be concluded that the material used for the artery forceps is fit for purpose.

The artery forceps broke at the end of the tooth region. Figure 4.7 compares the broken tooth with a pair of unbroken forceps to illustrate the fracture area. To analyse the reason of fracture, SEM images were taken to study the fracture surface. (Figure 4.8) No distortion is apparent in the image. A fracture propagation line on the cross section can be seen. The direction of propagation is marked in the figure.

The texture of the artery forceps' cross section indicates a brittle fracture initiated from the tooth side due to distortion. Brittle fracturing is usually caused by a rapid loading rate which the instrument could not withstand. It should only occur under abnormal use or could be due to poor manufacturing.

From experience, abnormal use would only take place when instruments are not designed fit for purpose. However, in this situation, other forceps within the same tray did not develop faults. It is considered that poor manufacturing was responsible for this. The most possible explanation is an initial flaw spreading and causing failure in use.

Figure 4.7 The broken jaw of forceps compared with an unbroken pair

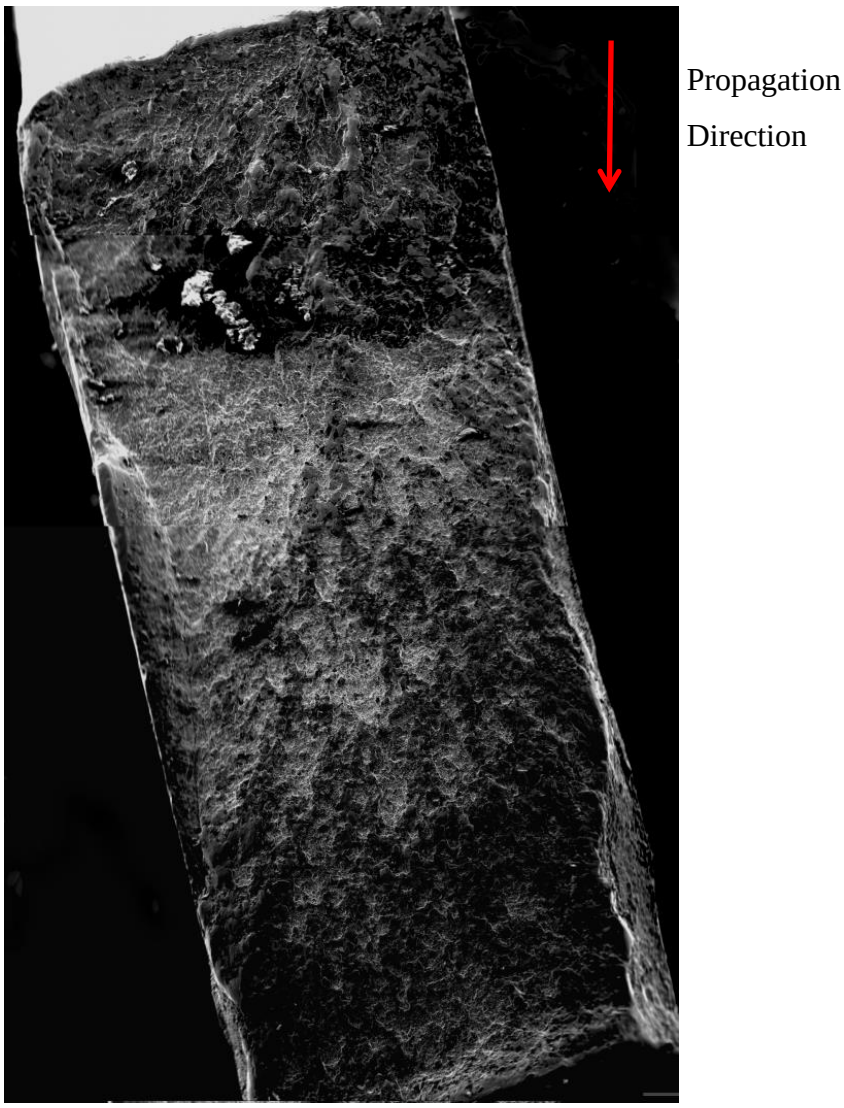


Figure 4.8 SEM image of the fractured cross section

4.3.2.2 Conclusion

The material used to manufacture the needle holders is not compliant with relevant British Standards due to having Al in it. Using inappropriate material is the main reason for corrosion. Poor manufacturing is responsible for the unexpected fracture. It is suggested that instruments should be opened widely for decontamination procedure. However when instruments' box joints are fairly tight when just purchased, leaving instruments open but not open to extremity of movement would be ideal.

4.3.3 Case Study – C

Spinal screws implanted in a patient failed at both ends of the screws. This case study aims at identifying the reason for failure.

Four screws were received for investigation. Two of them failed at the junction of coloured end while the other two failed both there and the tapping end. Figure 4.9 illustrates all screws received along with an image of the original product. The screws have two component parts, one tapping end for hole drilling and one coloured end for rod fixing. Due to the length of the screws, an unbroken one cannot fit into the SEM chamber. Two screws with both ends failed were tested as representatives of the situation. The other two screws with only the coloured ends broken were examined on their tapping side with regard to surface finish as an illustration of the original product quality.

For identification, analysed screws are named with an R- or L- determined by their insertion side, right or left. The two fractured cross section areas on each screw are named as C (Colour side) and T (Tapping side). Accordingly, the four cross sections are R-C, R-T, L-C and L-T.

Figure 4.9 Received screws (left) and image of the product (right)

Tests carried out include visual inspection, SEM imaging, and EDS analysis. It was not possible to reveal the morphology of L-C and R-C under an optical microscope due to their smooth texture. R-C was then imaged by SEM for texture analysis but L-C could not be imaged due to its length.

4.3.3.1 Results and Discussion

Details of the chemical composition as analysed by EDS can be seen in Table 4.4. It is seen that the chemical composition of the base material matches with the typical Titanium alloy Ti6Al4V, containing roughly 90% Ti, 6% Al and 4% V by weight.

Element	Al	Ti	V
Weight %	5.25	90.17	4.57

Table 4.4 Chemical composition of the screw's material

The surface finish on the two unbroken tapping screws was examined under the optical microscope. The surface finish of the screws was uniform, with no sign of machining or welding marks. It is thus speculated the two broken tapping screws would have a uniform surface finish as well, taking into consideration the manufacturing consistency.

It was not possible to observe the morphology of R-C's fractured area by optical microscope due to smooth texture and high reflection, hence images were taken by SEM (Figure 4.10). Figure 4.10 (b) is a zoomed in image of the central area where the red box is located in (a). It should be noted that the round edge appearing in Figure 4.10 is not from the sample but from the SEM sampling window. The screw's edge could not be captured in Figure 4.10, due to sample size.

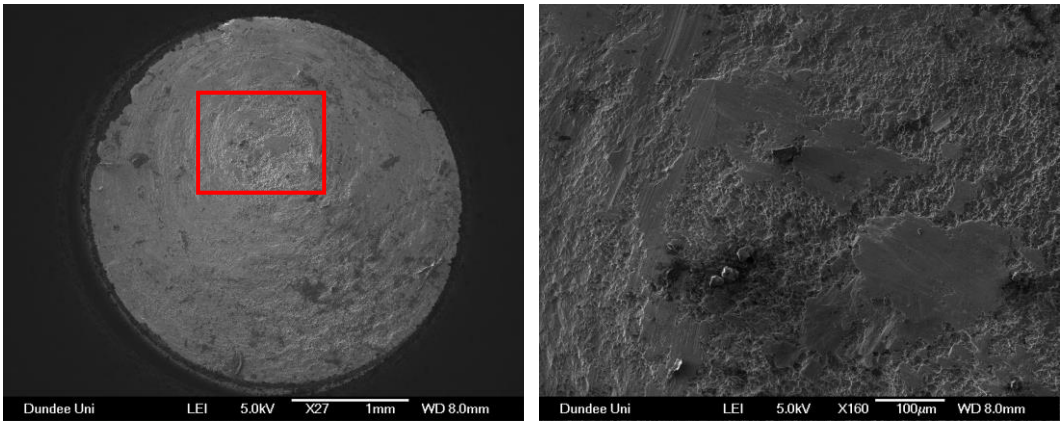


Figure 4.10 SEM image of R-C surface revealing two types of morphology
(a) Overview of fractured surface; (b) Image zoomed in from (a)

Two types of fracture structure, smooth and rough can be clearly seen in Figure 4.10. The smooth structures were faceted and plate-like with rough surface between each plate. The rough surface was characterised by microvoid coalescence (small dimples). Most dimples observed are not perpendicular, but are at a constant angle to the cross section surface.

Non-perpendicular dimples with constant angle are the features of ductile fracture caused by either a shearing or tearing tension. It is not possible to determine whether the root cause is shearing or tearing because it would depend on angle between dimples and

the cross section on the counter part of the screw. However, it might be determined by a user with the knowledge of how the screw is placed in surgery and the force.

Because the failure area is at the junction of the screw, it is suspected that it is due to a smaller cross section area that cannot withstand the applied load. Microvoids are then created by shearing/tearing with slow propagation. Faceted planes are generated rapidly when the screw can no longer withstand the stress.

The edge of R-C is then imaged and shown in Figure 4.11, where plastic deformation was observed. It indicates the end of fracture, i.e. where the screw breaks off.

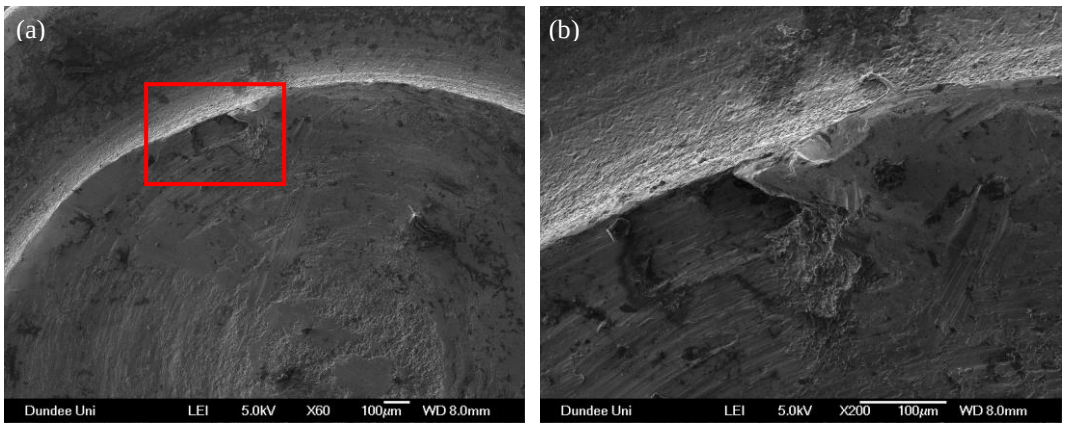


Figure 4.11 Plastic deformation on the edge of R-C
(a) Overview of fractured edge; (b) Image zoomed in from (a)

Figure 4.12 and Figure 4.13 are images of R-T taken by an optical microscope from 25x to 70x of magnification. Compared to R-C, R-T had a much rougher surface at the cross section and the structure could be easily revealed by optical microscope. The fractured area is separated into two zones by the reflection of light. Most of the cross section was shiny, producing specular reflection while some areas had little reflection and appeared almost black. Plastic deformation was also observed at the edge of R-T. River patterned cleavages could be seen at the bottom of the screw image, where there was little deformation.

Images of L-T are shown in Figure 4.14 and Figure 4.15. The fractured area shared very similar patterns with R-T, having even bigger plastic deformation and deeper cleavages.

Figure 4.12 Overview of R-T (25x) under optical microscope

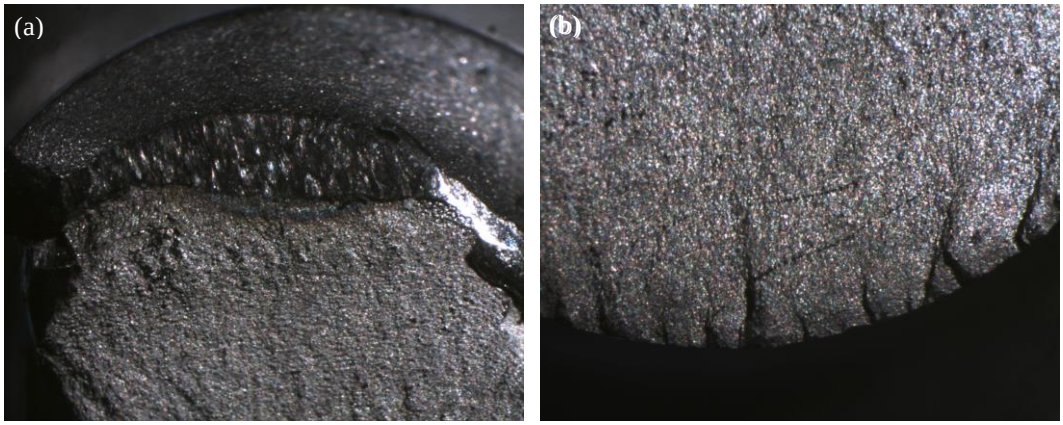


Figure 4.13 Detailed images of R-T
(a) Low reflection area (40x); (b) River patterned cleavages (70x)

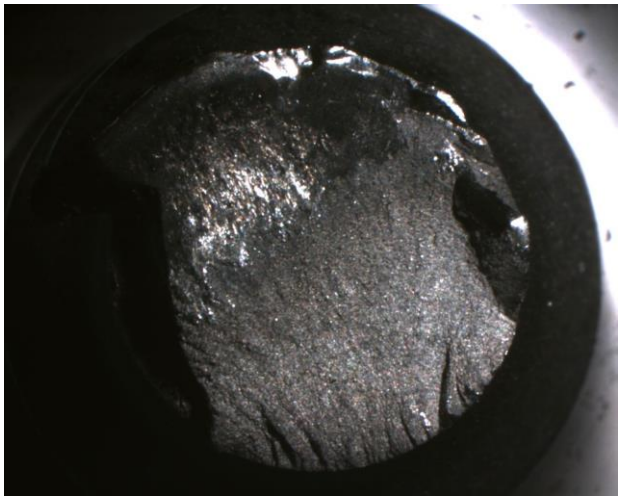


Figure 4.14 Overview of L-T (25x) under optical microscope

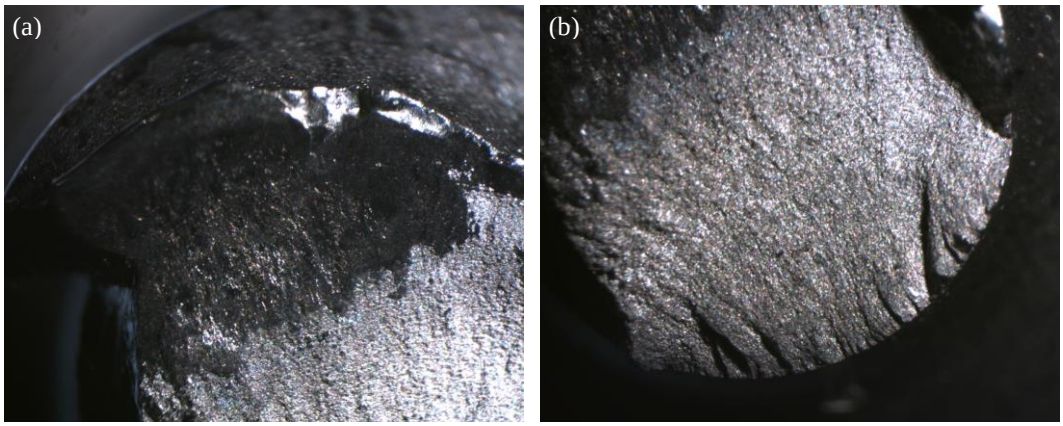


Figure 4.15 Detailed images of L-T
(a) Low reflection area (40x); (b) River patterned cleavages (40x)

R-T and L-T share highly similar patterns as described above. As stated above, plastic deformation indicates the end of fracture. The river-patterned cleavages are the features of brittle fraction, which is usually caused by a rapid loading rate. The direction of river-patterned cleavages aligns with the propagation direction, and lead to the plastic deformation area where the screw breaks off. It is also indicated by the river patterns that the crack is not caused by a twist along the screw but a stress perpendicular to the screw.

4.3.3.2 Conclusion

No concern is raised regarding the chemical composition of the material and no manufacturing faults were apparent.

Analysis of R-C indicates a shearing/tearing tension on the screw's junction, where the smaller cross section area cannot withstand the force. The crack was initiated with a slow propagation rate and eventual sudden failure.

Analysis of R-T and L-T shows that the crack was caused by a stress perpendicular to the screw with a rapid loading rate. The fracture mechanism is determined as bending fatigue.

Similar situations have been reported in literature over the past decades [81]. It is suspected that although the spinal physiological loading was firstly taken by the rods, some are then transferred to screws. It is suggested that since additional protection may be required at the bone/screw interface to reduce stress concentration, there may exists a need of designing a new spinal screw.

4.3.4 Case Study – D

A series of Incidents were reported regarding the instrument trays in a Catheterisation Laboratory. Initially, corrosion was observed on various instruments shortly after purchase. The root cause of this Incident was confirmed to be the use of saline solution. The use of saline was then stopped and all faulty instruments replaced, however corrosion was observed again shortly after. It was claimed by the staff that this had never occurred when using old mirror-polished instruments and their suspicion lay on the matt finishes. This case study aims at inspecting all possible factors that might have caused corrosion.

Corroded instruments consisted of a variety of types as well as there being a range of corrosion types. Instruments include scissors, artery forceps, retractors and clamps; corrosion types include rust stains and pitting corrosion. Figure 4.16 gives an example of the rusts observed.

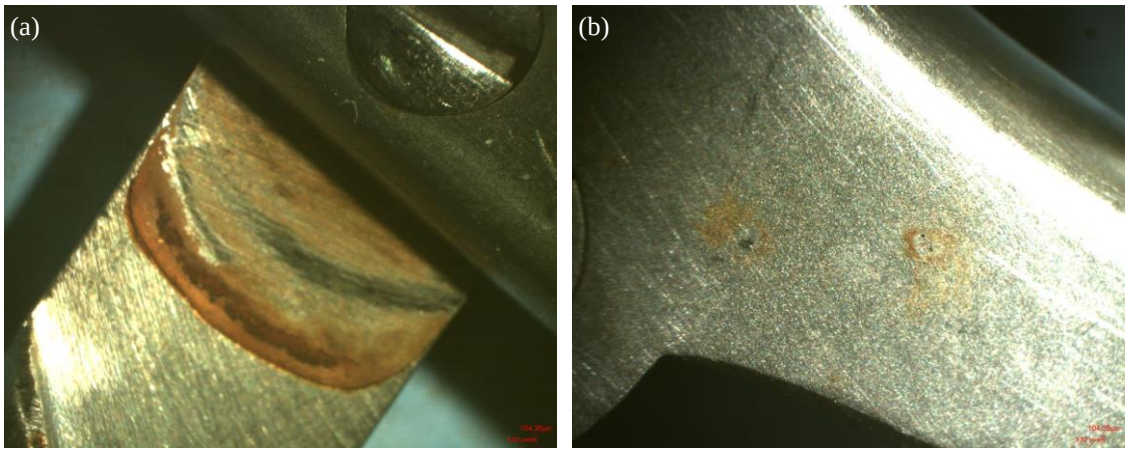


Figure 4.16 Example images of corroded instruments taken by optical microscope
(a) Rust stain on a pair of scissors; (b) Pitting corrosion on a retractor

Weight (%)	C	P	S	Si	Cr	Mn	Ni
Type D	0.42 – 0.50	0.04	0.03	1	12.5-14.5	1	1
Scissors	-	-	-	1.42	13.27	-	-

Table 4.5 Chemical compositions of Type D [42] and the tested scissors' unstained area

Some corroded instruments were examined by EDS and results showed that the material used is appropriate (Table 4.5). The manufacturer confirmed that no similar Incident was reported elsewhere hence it should not be caused by manufacturing faults. EDS results of stained areas did not show traces of possible corrosion source.

It was suggested that the rust stains might be caused by insufficient rinsing and long waiting time after surgery. Instruments were then repaired to remove the stains and put back into use. Additional rinsing was added during surgery using deionised water and PRE-KLENZ (Steris: Mentor, USA) was sprayed on instruments to keep moisture after surgery. However, rust stain was observed again shortly after although not as severe. Solutions containing aggressive ions such as Cl are usually responsible for pitting corrosion. However in this case, pitting corrosion occurred without the use of saline as well. On the other hand, a severely corroded clamp (Figure 4.17) was noticed in each reported tray. The clamp does not belong to the same manufacturer as other instruments and does not bear any markings. It is suspected that the corrosion on other instruments might be caused by the clamp due to potential difference.

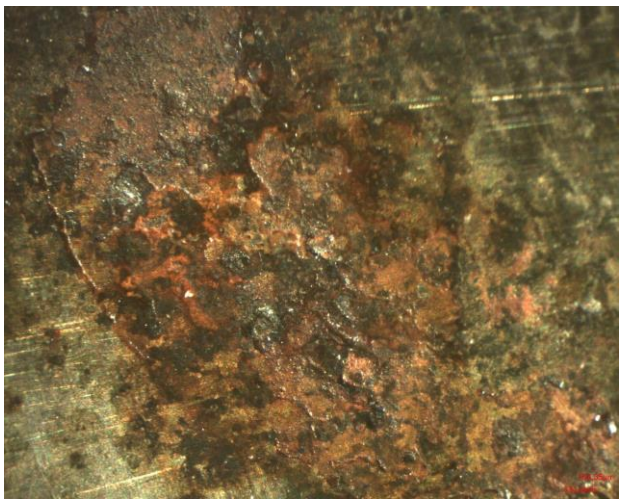


Figure 4.17 Rust observed on a corroded clamp

During investigation, the manufacturer was involved and further investigation was carried out by the manufacturer itself. Similar conclusions were reached by the manufacturer and no clear root causes was identified. It was then suggested by the manufacturer to run a one-month trial with repaired instruments (corrosion removed) but without the rusty clamp. Although no further corrosion was observed during the trail, theatre staff lost confidence in matt finished products and started to use disposable instruments instead.

4.4 Conclusion

From the Incidents investigated, it may be concluded that the failure of surgical instruments during use can result from various causes. Corrosion occurred in Case A,

caused by blood being left on instruments; corrosion occurred in Case B, caused by substandard material used; unexpected fracture on instruments in Case B was most possibly due to manufacturing flaws; and the breakage of spinal inserts in Case C may be solved by a new design. Although no root cause was identified for Case D, it is worthy to look at the differences brought by surface finishes of surgical instruments.

Once surgical instruments are put into use, the factors influencing their behaviour are many and individual inconspicuous effects can add up and trigger something serious, such as corrosion leading to an unexpected break.

Chapter 5 Properties of Surgical Instrument Surface

During the course of this work it became apparent that there was debate about the effect of surface finish on instrument drying and corrosion resistance. Matt finish is applied to instruments to reduce reflection. This is particularly relevant for laparoscopic instruments but it may also be applied due to fashion. The instrument may feel better to the touch or look more refined. At least one manufacturer matt finishes all their instruments as a matter of policy. Other, sometimes more traditional manufacturers maintain that polished finishes dry more readily and are therefore more corrosion resistant. This of course may be partially driven by it being easier for them to mirror finish than to provide a guaranteed consistent high grade matt finish. User prejudice was clear in case study D in section 4.3.4. Apart from surface finishes, the effect of disinfection cycles on surgical instruments remains unclear as well. The suggestion of not routinely use alkaline detergent [2] has not been either widely accepted or proved. Moreover, although it is well known that passivation can enhance the corrosion resistance of instruments, how it changes instruments behaviour in disinfection cycles has not been studied.

It is known that the mechanical characteristics of a material are governed by its bulk composition while how it interacts with the environment is dependent on the surface properties [82]. For surgical instruments, the properties mentioned above lead to a characterised behaviour in the surgical reprocessing environment. Hence, this chapter concentrates on how different surgical steels with surface finishes and treatments behave in the disinfection process and how that process changes the behaviour of surgical steels. First, a qualitative study is conducted to determine the effect on instruments with various finishes brought by disinfection processes. Based on the result of the first study, a more comprehensive experiment is designed to quantify the changes in instrument behaviour caused by all factors mentioned above: steel types, surface finishes, disinfection and passivation processes. To quantify the instruments behaviour, three parameters are selected: apparent contact angle to indicate wettability, evaporation mechanism to illustrate drying process and Cr enrichment at the surface to demonstrate passivity.

5.1 Qualitative Study on the Passivity Change of Instruments

5.1.1 Passivity of Stainless Steels

As described in previous chapters, there is still debate over the effect on instruments of the alkaline detergents used in CSSDs across the UK. However few studies aim at studying its effect. Mainier et al. [83] studied the behaviour of various instruments in decontamination procedures, however inadvertently discovered the material used to manufacture those instruments did not comply with what was claimed by suppliers. It was also noted that the cleaning solutions used in Brazil are usually chlorine-based oxidants. Cisse et al. [82, 84] reported that the oxide layer formed on mirror-polished 304L surfaces is much thicker on ground ones. However the experiment is conducted by exposing samples in 400°C steam for 500 hours and hence the conclusion cannot be directly applied onto this study.

Therefore, an initial study was carried out to examine the effect of the disinfection process with the alkaline detergent as part of the procedure. The aim is to give an indication as to whether the disinfection process used helps to build up a passivation layer on surgical instruments or provides negative effect and will therefore corrode surgical instruments eventually.

The passivity of sample surfaces is chosen to indicate the changes on surgical instruments as it measures the state of metal surfaces. Most metals without any surface treatment are in the active state, which allows direct dissolution of the metal ions into electrolytes. On the other hand, the passive film adhered on the material surface can prevent such dissolution by separating the metal substrate from the environment [80].

The purpose of transiting material surface from active to passive state is to enhance corrosion resistance. There exist many different methods to achieve this, such as coating and nitriding [85]. Although these methods are mature techniques and sometimes have additional benefits such as lower bacteria adhesion, they are usually applied on surgical implants but not on instruments. This is due to instruments' low unit price and their limited contact time with aggressive solutions compared to implants. Hence, transiting the surfaces of surgical instruments from active to passive state is usually accomplished by the most economic method, passivation.

Passivation is an oxidation treatment where metals are bathed in nitric acid or citric acid solution under certain temperature for about 30 minutes. A thin layer of passive film can be generated by the procedure. On the other hand, the transition from active to passive state can be accomplished by other means as well. It even naturally happens under dry environments containing Oxygen, although the passive film grows much slower. Both passive films and rust are the product of oxidation processes, but they differ from each other greatly. Passive films are often very thin (within several nm) and invisible to naked eyes while rust layers are much thicker (can grow to several hundred μm) and can be easily identified by naked eyes. Moreover, passive film functions as the barrier against corrosion while rust is usually accompanied by pits or crevices that compromise the mechanical property of instruments [86].

Although passive layers formed on pure metals such as Fe are not stable, the ones formed on Cr alloys can be maintained for a long period of time [86]. Stainless steel [87], defined as an alloy of Fe containing "at least 10.5 percent of Chromium", is one typical type of the mentioned Cr alloys. Although the introduction of Cr dramatically enhances the corrosion resistance, it makes Fe alloys "stain less" but not "stain proof". It is understood that higher concentration of Cr shows better resistance to corrosion (Fe alloys consist of more than 30% Cr are reported to be corrosion free in 1M HCl) [86], but the level of Cr added to the alloys highly depends on the mechanical property required for the application. Therefore, a Cr-rich oxide layer adhered to the alloy surface can greatly increase the corrosion resistance without compromising its mechanical properties [82, 84]. With the enrichment of Cr at surface, the proportion of Fe reduces. Hence, the atomic ratio of Cr/Fe is typically used to indicate the sample's ability of resisting corrosion [88-90].

Another factor might impact the passivity of stainless steel surfaces is roughness. Abosrra [91] studied the corrosion resistance of 316L stainless steel in NaCl solutions with three different roughness and concluded that smoother surfaces have better corrosion resistance. Similar results were reported by other studies as well with various stainless steel types and under various environments [84, 92-95].

Therefore, Cr/Fe ratio is selected to indicate the passivity of surgical instruments in this study. Samples used in this experiment were not passivated. Results give a straightforward indication of roughness and the effect brought by the disinfection

process.

5.1.2 Experiment Setup

Samples were prepared from commercial stainless steel 420 in sheet form and were cut to 20 x 40 mm. The chemical composition is given in Table 5.1.

	C	P	S	Si	Cr	Mn	Ni
Weight (%)	0.42	0.200	0.007	0.29	13.69	0.33	0.08

Table 5.1 Chemical compositions of stainless steel 420

Four different surface finishes were prepared to achieve both mirror-like and reflection-reduced surfaces. Three different grades of silicon carbide abrasive sheet (P1200, P600, P320) and one type of glass bead (B10 with particle size of 180-300μm) were used for finishing. Roughness of the samples was measured by a Dektak 3ST profilometer (Veeco: Plainview, USA) at a random direction across the surface, and a mean of 10 readings taken. A Jeol JSM-4700F SEM (Jeol: Tokyo, Japan) was used at 10kV to determine the characteristic appearance of the surface finishes. The morphology of prepared samples can be seen in Figure 5.1.

To mimic a typical one-year of use samples were put through the washing cycle 150 times. Samples were aligned in a stainless steel washing basket (manufacture and material unknown due to long service period) prior to disinfection processes.

1. Pre-washed in cold water at 25°C for 6 minutes
2. Hot-washed in 65°C water for 16 minutes, with detergent added
3. Rinsed in 70°C water for 2 minutes
4. Disinfected in 90°C RO water for 1 minute and
5. Dried in 110°C hot air for 10 minutes

The detergent used in the procedure is Maximum pH Plus (Serchem: Telford, UK), with a pH value of 13-14 and diluted to about pH 10.5 at point of use. Samples were degreased in an acetone bath for 5 minutes, rinsed in deionised water for 5 minutes and dried in air prior to any measurement.

To analyse the relationship between the concentration of chemical composition and depth from surface, depth profile analyses were performed on samples by a Glow

Discharge Optical Emission Spectroscopy (GD-OES) (Horiba Jobin Yvon: Kyoto, Japan). To obtain the relationship between chemical concentration and distance from sample surface, the material is targeted by Argon ions, sputtered into powder and then analysed according to wavelength. The power applied was 50W and the pressure 850Pa. The sampling size was 15mm diameter.

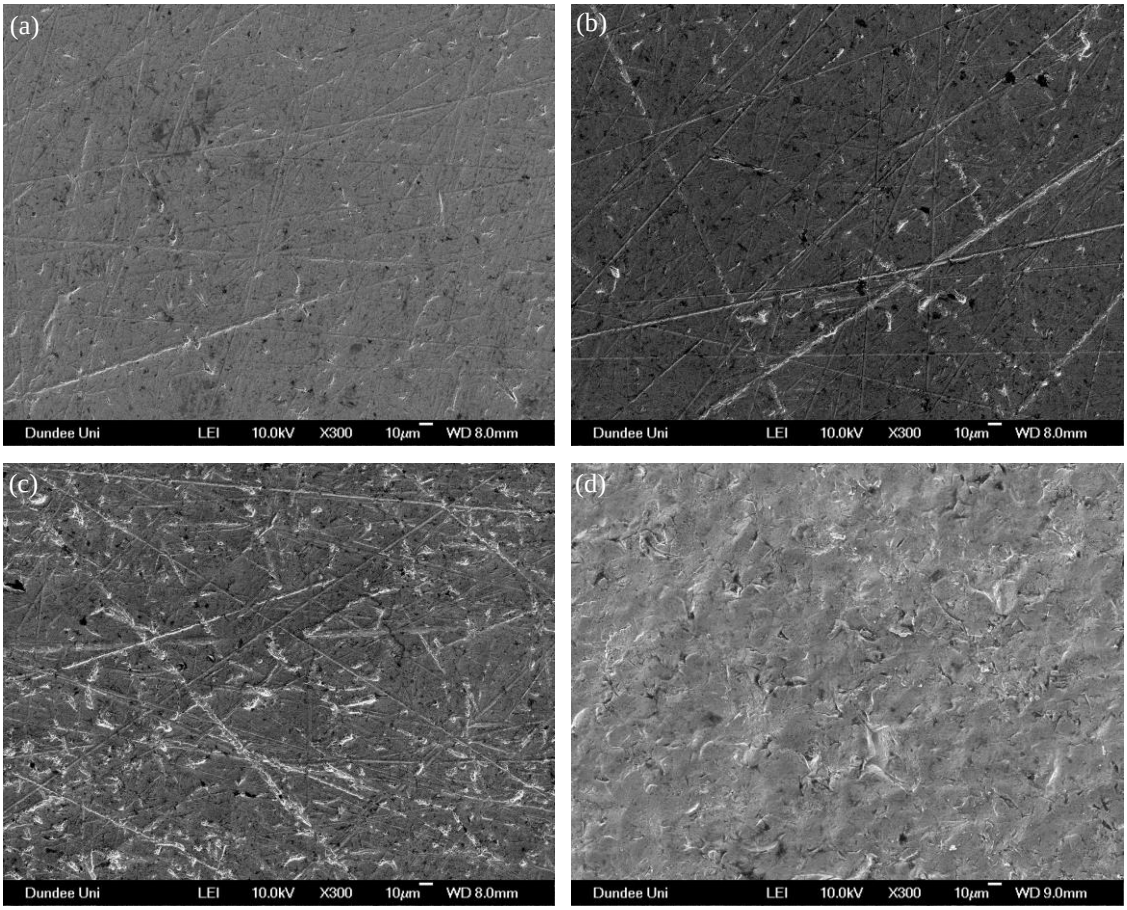


Figure 5.1 SEM images of different surface finishes
(a) P1200, (b) P600, (c) P320, (d) B10

5.1.3 Results and Discussion

SEM images taken of different polished surface finishes (Figure 5.1) indicated similar morphological features among all three polished samples except fewer and shallower scratches with the finer polishing grade. The bead blasted sample surface was not characterised by scratches but indentations left after blasting.

Ra (nm)	P1200	P600	P320	B10
Before	46.34±5.0	62.51±6.7	126.00±13.7	731.46±37.1
After	43.2±2.8	59.2±1.9	122.2±15.3	727.0±24.3

Table 5.2 Roughness of samples both before and after disinfection processes

Roughness of the sample surfaces was determined by Ra values before and after the disinfection processes. It can be seen from Table 5.2 that the roughness of the samples was not changed significantly by the disinfection processes.

Discolouration was observed on B10 samples after 150 cycles of disinfection processes (Figure 5.2). It is believed to be discolouration but not corrosion hence no further concern is raised.

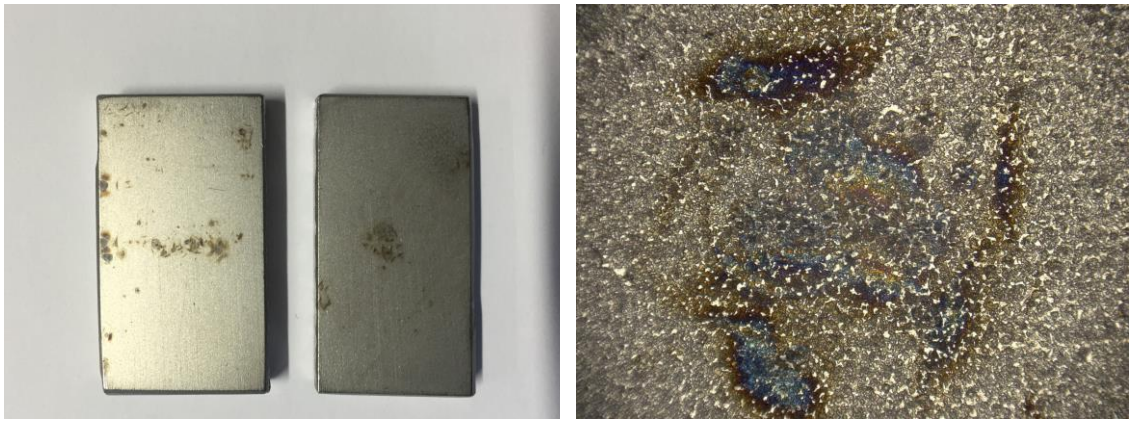


Figure 5.2 Discolouration observed on B10 samples

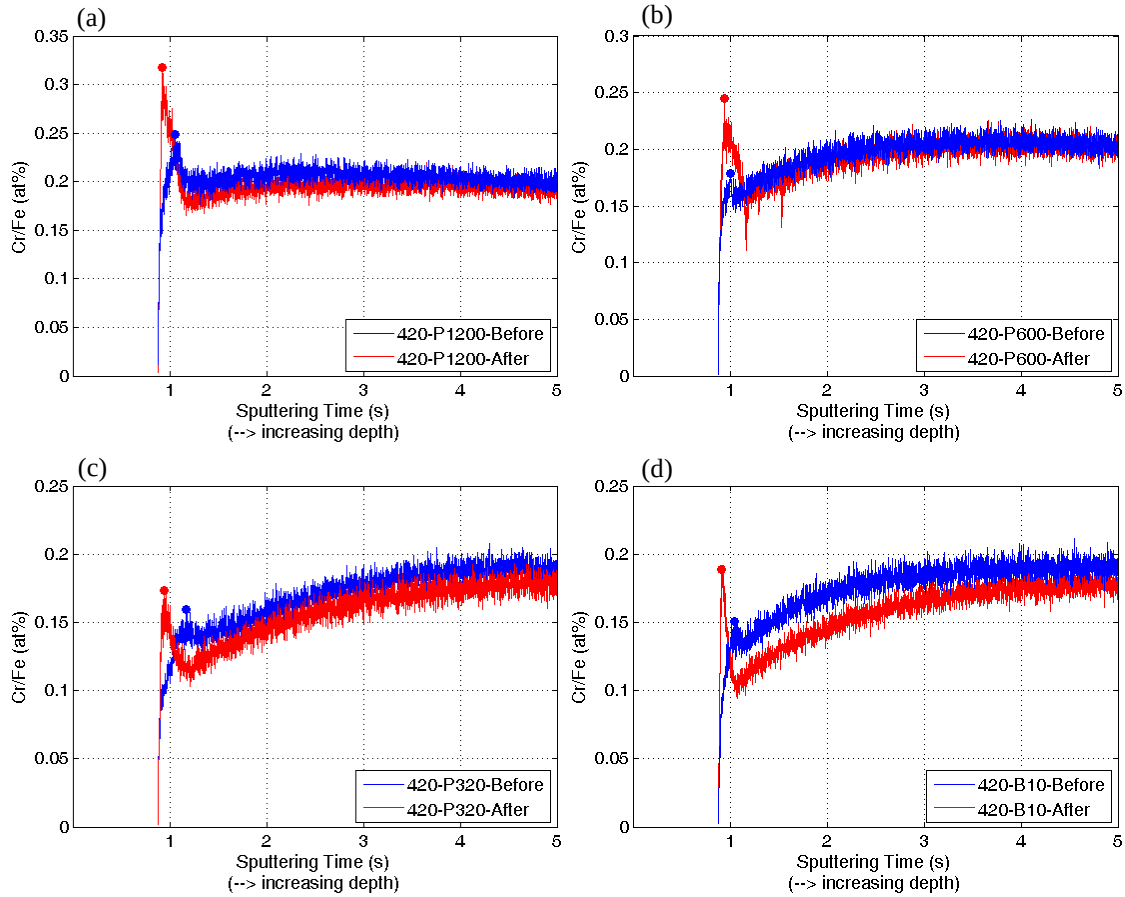


Figure 5.3 Cr/Fe value by sputtering time, where red/blue dots represent the peak value at sample surface (a) P1200, (b) P600, (c) P320, (d) B10

The concentration of elements was detected before and after experiments and the Cr/Fe ratio was calculated to indicate the passivity of sample surface. Figure 5.3 shows the changes brought by disinfection processes. The blue line indicates the Cr enrichment of samples prior to disinfection processes and the red line is the result of samples after disinfection processes. The time taken to sputter gives a measure of distance from the surface.

A peak value is observed on each sample, at before 1.2s. It is marked by a red/blue dot in Figure 5.3. This illustrates the Cr enrichment at the sample surfaces due to finishes and treatment and is the indication of surface passivity. Among all samples, P1200 showed the most significant effect in Cr/Fe ratio increasing from 0.24 to 0.32, followed by P600, whose Cr/Fe ratio changed from 0.18 to 0.23. P320 displayed the least increase of the three polished samples with just more than 0.01. B10 has a minimal change in Cr/Fe ratio. Changes of Cr/Fe ratio caused by disinfection process only have an effect within a few microns of the surface (displayed on figures from 0.8s to about 1.2s), before the Cr/Fe ratio of the material reaches back to its bulk compositional ratio.

All samples showed an increase of Cr/Fe ratio at the sample surfaces, indicating that the washing cycle using alkaline detergent have a positive effect on corrosion resistance of polished stainless steel type 420. The effect ranks as P1200 > P600 > P320 > B10.

By combining roughness results and depth profile of the samples, it may be concluded:

1. Currently disinfection processes with alkaline detergents have a positive effect on stainless steel 420;
2. The effect increases as roughness is reduced;
3. The disinfection processes do not change the surface roughness significantly.

This initial experiment is a qualitative study that proves the positive effect of disinfection processes on the passivity of surgical instruments. However the limitation of this initial experiment is in the surface preparation. Prepared finishes in this study are not as applied on commercially available products. Moreover, the changes in instruments behaviour are not quantified. Therefore, based on this initial experiment, a more comprehensive experiment was designed and conducted.

5.2 Quantitative Study on the Change of Instrument Behaviour

In this study, more grades of stainless steel as used to manufacture surgical instruments are included. The work was carried out with the collaboration with several manufacturers using commercial surface finish grades. Samples with passivation layers were also studied.

To quantify the effects brought by disinfection processes and to study the detailed surface properties of surgical instruments, two more parameters were introduced to the experiment apart from passivity: wettability and evaporation mechanism. Wettability, characterised by contact angle, measures the likability for a water to stick on a instruments. Evaporation mechanism, illustrated by changes in droplet dimensions such as contact angle and baseline length, explains the behaviour of water droplet under certain temperature and gives an indication of the total length needed to fully dry a piece of instrument.

The factors might influence the experiment results are introduced below, for a better choose of the experiment setup and for a consistent result.

5.2.1 Wettability

Wettability measures the ability for a liquid to spread on a solid substrate. It is a significant property in a large number of applications, including printing, painting, coating, soldering and lubrication [96, 97]. For example, hydrophobic coatings painted on wood that repel any form of liquid greatly extend the lifetime of wood exposed to the elements.

When a liquid drop is placed on a solid substrate, the droplet shape is affected by many factors, such as surface tension, gravity and the properties of the substrate. Inside the drop, each molecule shares tension equally, creating a net force pulling each together. However, molecules at the surface of the drop are only pulled inwards because they are not surrounded by neighbours. The smaller the surface area, the fewer molecules are exposed to the surface and hence the less energy is required to keep the drop whole. Combining with other factors, equilibrium will be reached when the minimum energy is required to retain the drop shape. The energy required here is called the *Global Energy Minimum* (GEM) [98].

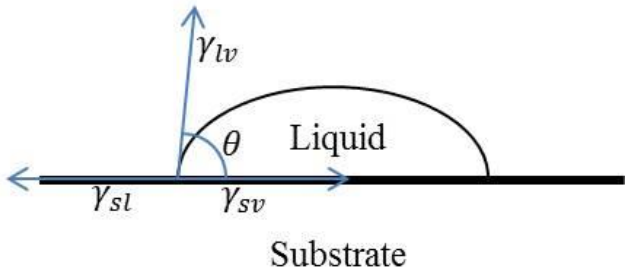


Figure 5.4 Illustration of a liquid drop on a solid substrate, where θ is the contact angle, γ_{sv}, γ_{sl} and γ_{lv} are the surface tensions at the interface of solid/vapour, solid/liquid and liquid/vapour respectively

The contact angle at equilibrium [97], defined as "the angle between the tangent drawn at the triple point between the three phases and the substrate surface" (Figure 5.4) is used to describe the degree of wetting and is an indication of surface hydrophobicity. At certain droplet volume, contact angle decreases as contact diameter increases.

Contact angle is categorised into four types (Figure 5.5):

- Complete wetting ($0° < \theta < 10°$)
- Partial wetting ($10° < \theta < 90°$)
- Partial non-wetting ($90° < \theta < 150°$)
- Non-wetting ($150° < \theta < 180°$)

Complete wetting appears when the contact angle is less than 10° while non-wetting occurs when the contact angle is greater than 150° [99]. The lotus effect is one example of non-wetting where the super-hydrophobic surface of a lotus leaf lets a water droplet roll freely, carrying away contamination and hence achieving of self-cleaning. A contact angle <90 indicates a hydrophilic solid substrate and a contact angle >90 indicates a hydrophobic one.

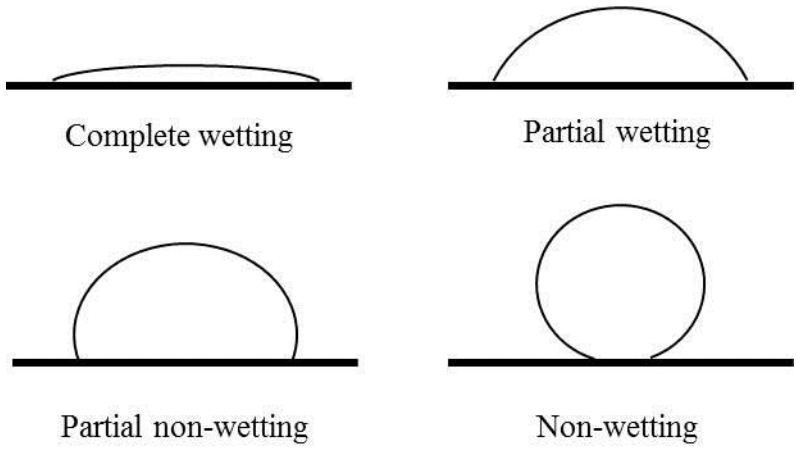


Figure 5.5 Four wetting types illustrated by the shape of liquid droplet

5.2.1.1 Wetting of Ideal Surfaces

An ideal surface is smooth, flat, chemically homogeneous, non-reactive and insoluble. The factors governing contact angles on ideal surfaces [96, 98, 100] are the characteristics of the materials involved, i.e. chemical composition of the surface material and viscosity of the liquid and temperature.

The contact angle of a specific liquid on a specific ideal surface is unique. A drop of liquid placed on a solid surface will spread until equilibrium is reached [101]. The status can be described by Young's equation:

$$\gamma_{sv} = \gamma_{sl} + \gamma_{lv} \cos\theta \tag{5.1}$$

where γ_{sv}, γ_{sl} and γ_{lv} are the surface tensions at the interface of solid/vapour, solid/liquid and liquid/vapour respectively. The contact angle is a direct result of the surface tension and this model was developed by Thomas Young (1773-1829) [102].

5.2.1.2 Wetting of Non-ideal Surfaces

However, very few surfaces are ideal and then the model described by Young does not fit. In non-ideal situations, more factors must be included, particularly surface roughness [97, 99, 100].

To include roughness, Wenzel [99, 100] created a refined model based on Young's equation:

$$\cos\theta_w = r\cos\theta = r\left(\frac{\gamma_{sv}-\gamma_{sl}}{\gamma_{lv}}\right) \tag{5.2}$$

where θ_w is the observed contact angle and r is the non-dimensional surface roughness factor. r is defined by the ratio of the actual contact area to its projected area:

$$r = \frac{A_{sl}}{A_f} \tag{5.3}$$

As r is always greater than 1, $\theta_w > \theta$ on hydrophobic surfaces and $\theta_w < \theta$ on hydrophilic surfaces. The wetted area increases for hydrophilic surfaces and decreases for hydrophobic surfaces. The model indicates that under such situations, hydrophobic surfaces would behave more hydrophobically while hydrophilic surfaces would behave more hydrophilically [103].

Wenzel's model explains the wetting phenomena on rough surfaces when all holes on the surface are filled by liquid (Figure 5.6). To include the situations where holes on the surface may be filled by air instead, Cassie and Baxter [99, 100, 104] introduced two more elements into Wenzel's equation, f_{sl} and f_{lv}:

$$\cos\theta_{CB} = f_{sl}\cos\theta_{sl} + f_{lv}\cos\theta_{sv} \tag{5.4}$$

$$= f_{sl}\cos\theta_{sl} + f_{lv}\cos 180^{\circ} \tag{5.5}$$

$$= f_{sl}\cos\theta - f_{lv} \tag{5.6}$$

where f_{sl} is defined as the solid/liquid contact area divided by the projected area and f_{lv} is defined as the solid/vapour contact area divided by the projected area.

Both Young's and Wenzel's equations are included in Cassie-Baxter's equation, when $f_{sl} \to 1, f_{lv} \to 0$ and $f_{sl} \to r, f_{lv} \to 0$ respectively.

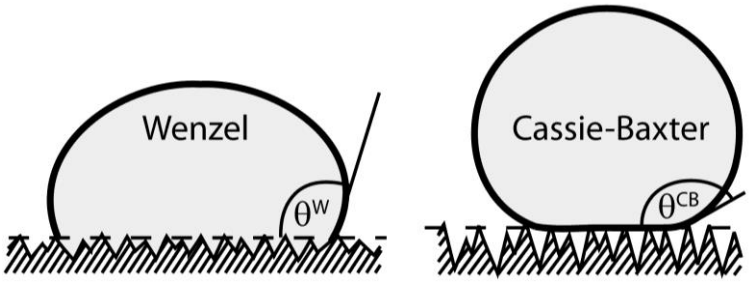


Figure 5.6 Wetting considering roughness (left: Wenzel type; Right: Cassie-Baxter type) [101]

While the Wenzel state is usually used to describe the behaviour of water droplets on hydrophilic surfaces, the Cassie-Baxter's equation has been widely used to predict contact angles on hydrophobic surfaces, especially super-hydrophobic surfaces.

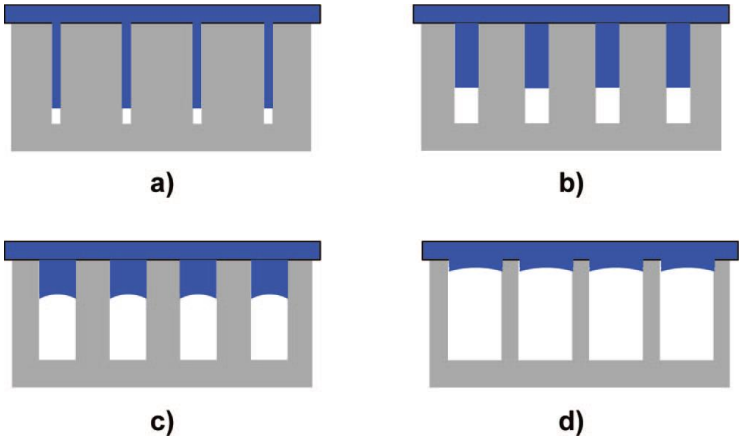


Figure 5.7 Illustration of intermediate wetting states between Wenzel and Cassie-Baxter state. [103] (a) near Wenzel state; (b) intermediate state dominated by Wenzel behaviour; (c) intermediate state dominated by Cassie-Baxter behaviour; (d) near Cassie-Baxter state.

However in the real world situations, few surfaces are wetted by only Wenzel mode or Cassie-Baxter mode. Transition between the two states and intermediate wetting states are observed (Figure 5.7) [103]. The behaviour of water droplets is hence a mixture of the two states.

As roughness is one of the most important factors that change the behaviour of liquid drops, many studies have reviewed the effect of roughness on various materials. Meiron et al. [96] measured the contact angle on glass slides with a roughness ranging from 1.3 to 11.2 μm. An increase of the contact angle was observed with roughness. A similar phenomenon was observed by Tamai and Aratani [105]. Kubiak et al. [102] expanded the study to six different materials, including Al, Titanium, Fe and Copper alloys, ceramic and PMMA. Within the roughness range from 0.15 to 7.74 μm, a minimum value of contact angle was observed in each case. It was concluded that the contact angle will reduce with roughness to a limit, and then increase with roughness. However, the roughness value corresponding to the minimum contact angle value varies with material. A similar behaviour was reported in Kandlikar and Steinke's research [106] for copper but not for stainless steel. Other literature such as Busscher's study [100, 107] indicates that surface roughness values smaller than 0.1 μm does not have an influence on contact angle values.

It can be concluded that although the effect from roughness varies from material to material, roughness itself can be defined as an inherent factor of the substrate surface.

5.2.1.3 Factors Affecting Contact Angle Measurement

In non-ideal systems, the stability of the contact angle measured depends on many factors, including cleanliness of the surface, size of the liquid drop and direction of observation.

It is well known that heterogeneity of the substrate surface contributes to instability. In addition to the inherent heterogeneity of the material, contaminants or dust particles adhering to the surface will increase the heterogeneity significantly. Kandlikar et al. [106] reported that the contact angle measured on a platinum surface after cleaning with acetone and distilled water (61°) was much bigger than that was measured after aggressive cleaning (22°) with NH_4OH and H_2O_2. Hierro-Oliva et al. [108] studied the difference in contact angle brought about by various preparations. In

the experiment, 5 sets of samples were prepared. Details of the cleaning steps used are shown in Table 5.3. Contact angles of sample set 1 showed a high dispersion, ranging from 46° to 73° while contact angles of sample set 2 ranged only from 40° to 45°. A longer drying time does not affect the contact angle as results measured of sample set 2 and 3 are very similar. The same consistency was also seen in sample set 4 and 5. However, contact angles measured from the two drying methods are quite different but consistent, with samples dried by Nitrogen (sample set 2 and 3) having a contact angle between 40° to 45° and samples dried in the oven (sample set 4 and 5) having a contact angle between 60° to 65°. The underlying theory causing contact angles changes was not suggested. Therefore, keeping to a consistent drying technique is crucial for consistent results.

Set	Rubbing	Ultrasonic Cleaning	Drying Method	Drying Time	Wash between Measurement
1	√	√	N_2	60mins	√
2	×	√	N_2	60mins	√
3	×	√	N_2	120mins	√
4	×	√	Oven	60mins	√
5	×	√	Oven	120mins	√

Table 5.3 Details of sample preparation in Hierro-Oliva's study [108]

Other than sample preparation, different system setups would also cause diverse results. The differences in experimental setup include measuring duration, direction of observation and droplet size. Below explains how these factors influence the contact angle result.

Spread is the first stage of liquid behaviour after dropping onto the substrate. Spread is accompanied by a decrease of contact angle and an increase of contact area. Spread may be stopped by various processes, such as solidification, chemical reaction with the substrate, absorption by the substrate or, most commonly, attainment of natural equilibrium. Evaporation, barely discernible at room temperature, continues throughout the whole process. Raising the temperature can significantly speed up evaporation [97]. A defined duration of time required for spread cannot be identified as it is governed by liquid and substrate properties. Kubiak et al. tested the difference of contact angle at 0s and 20s and a decrease of contact angle was recorded. However, the trend of contact angles for various surface roughness remained the same [102, 109]. It is suggested that

a slight change of the time between placing liquid drop and measuring contact angle would not significantly change the results or conclusions, as long as vaporization is negligible and all experiments are carried out under the same conditions.

Surfaces in non-ideal systems are heterogeneous and the morphology of the surface is irregular. It is reasonable to predict that the apparent contact angle observed from various directions can differ. A typical example would be a polished surface with directional grooves. Liquid drops prefer to spread along the grooves instead of across, as less energy is required (Figure 5.8). Decker et al. [110] and Mieron et al. [96] proposed a method of measuring contact angles. By giving a vertical vibration to the sample, the liquid drop gained sufficient energy to become circularly symmetric. The contact angle measured by such a method matched Wenzel's model. However, this method requires sophisticated equipment: a motor controlled plate providing delicate vertical vibration and a camera providing top-view images to check drops achieve symmetry. It has also been proven that the GEM can be reached when the size of the drop is large enough compared to surface's roughness scale and thus, extra equipment is not necessary. Kubiak et al. [102, 109] were able to obtain consistent results by applying drops of $4 \pm 0.5\ \mu l$ to test surfaces and recording contact angle data from one particular side (perpendicular to the surface texture direction). Figure 5.9 is an illustration of camera's direction of view.

To summarise, achieving stable contact angle results with low dispersion requires the consistency in many setup details. It includes surface cleaning method, drying technique, duration between water dropping and measurement, direction of observation and droplet size. These factors are hence considered and detailed in this study.

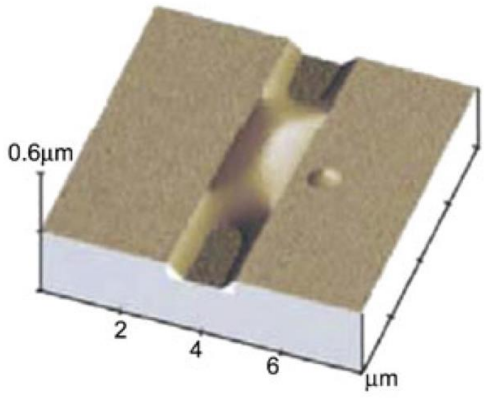


Figure 5.8 Liquid drop spreading along surface grooves and creating an asymmetric shape [98]

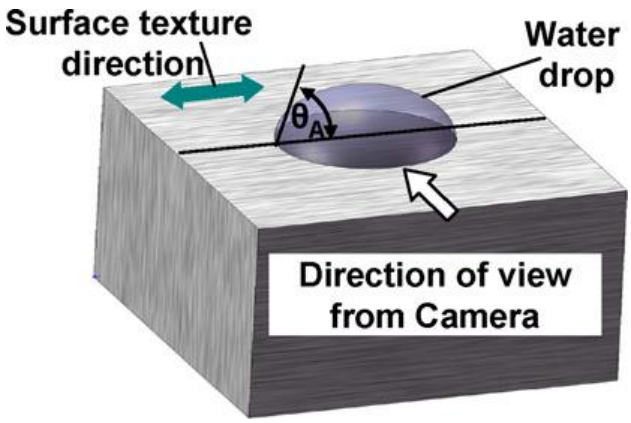


Figure 5.9 Diagram of camera's direction of view in Kubiak's study [102, 109]

5.2.2 Water Evaporation on Heated Surfaces

Liquid evaporation is a process happens naturally when the atmosphere around the liquid drop is not saturated with its vapour [111-113]. It is a very important topic not only because it occurs in the natural environment such as rain, fog and snow but also because of its wide engineering applications, such as spray drying, rapid cooling, printing, washing and coating.

Although there are also some studies carried out to study the water evaporation on heated surfaces [106, 114], they are all conducted under very high temperatures that would lead to an instant evaporation within seconds. To the best of our knowledge, no experiment was performed to suit our specific temperature and application. Considering the temperature used in this study is below 100°C, studies carried out at room temperature might give a better interpretation of the evaporation mechanism as the only difference lies in it not being accelerated by elevated surface temperature.

A sessile drop is usually used to study drop evaporation. A sessile drop [112] is defined as "a drop which is deposited on a solid substrate where the wetted area is limited by a contact line". The changes of contact angle and contact line radius are usually recorded to understand the evaporation mode of the drop.

As early as in 1977, Picknett and Bexon [115-118] observed two modes for liquid evaporation on solid substrates and defined them as a constant contact angle (CCA) mode and a constant contact area (CCR) mode. In the CCA mode, the contact angle of the liquid drop remains unchanged while the contact line radius decreases with evaporation. On the contrary, in the CCR mode, the contact line radius is kept at the

original value while the contact angle decreases with evaporation. The two modes were also confirmed by other researchers including McHale and Bormashenko [113, 116, 119].

A third mode, also known as the stick and slip mode, was found on various liquid drops evaporating on many types of substrates. In essence, the stick and slip mode is a mixture of the CCA and CCR mode [116, 117]. Throughout the evaporation process where the stick and slip mode appears, four stages (Figure 5.10) were distinguished by Bourges-Monnier and Shanahan [111, 115-118]. The first stage (stage I) was observed just after the sessile drop being placed. In stage I, the surrounding environment is saturated by a vapour source and, hence, little change is observed in contact radius and contact angle. After the vapour source is removed, a second stage (stage II) is characterised by a more rapid evaporation rate, with the contact angle decreasing and contact radius constant. Stage III starts at the depinning of the contact line. Similar to the CCA mode, the contact angle stays constant while the contact radius decreases quickly. Stage II and III (the stick and slip mode) can be observed repeatedly within one evaporation process. Finally, the contact angle and contact radius decrease simultaneously in Stage IV.

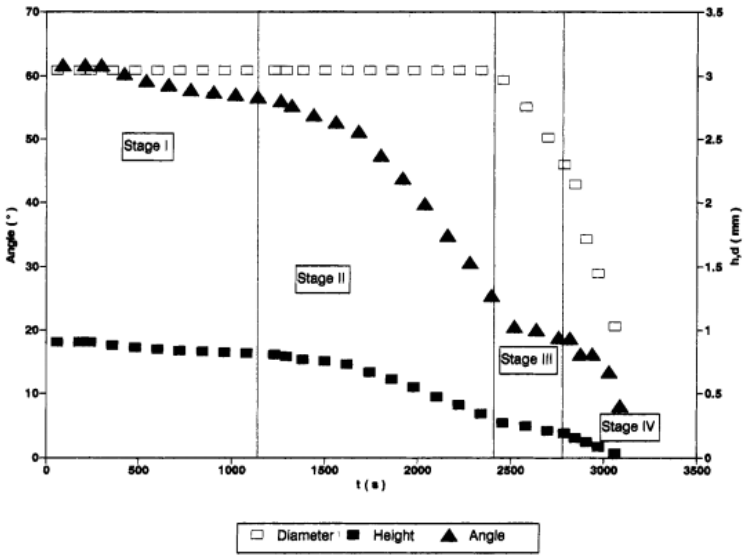


Figure 5.10 Four stages of evaporation observed by Bourges-Monnier and Shanahan [111]

While the exact mechanism of contact line pinning and depinning is still under debate, many factors are known to influence the evaporation process. Fang et al. [118] discussed the effect of droplet size, as larger sessile drops placed have a longer initial contact line than smaller ones, although their initial contact angles are similar. Birdi, Vu

and Winter [113] pointed out that the drop's wettability on the substrate has an impact on the evaporation. When the original contact angle is greater than 90°, the evaporation mechanism matches the CCA mode. On the contrary, CCR mode was observed for water droplets with initial contact angles smaller than 90°. Bormashenko [116] focused on the differences caused by substrate surface energy level. It was concluded that high-energy surfaces such as metal show evaporation processes similar to CCR mode while low-energy ones show a stick and slip mode. Figure 5.11 shows the imaged evaporation process with different mechanism [117].

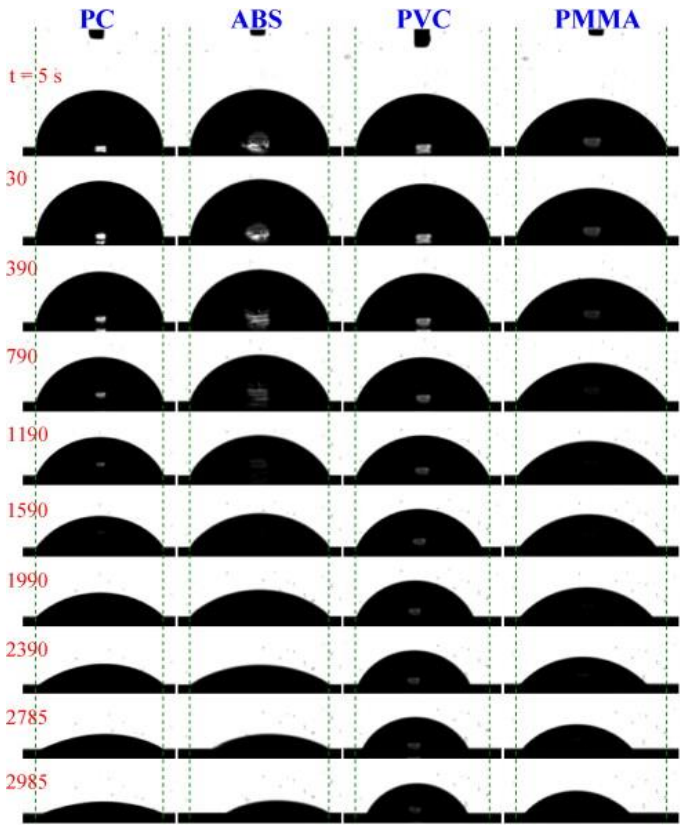


Figure 5.11 Observed water droplet evaporation behaviour with time on various substrates, including PC, ABS, PVC and PMMA [117]

Beside all the factors mentioned, roughness is also widely studied to understand its effect on the evaporation mechanism. However various results are observed. Some observed a significant decrease of the contact angle during the evaporation process [119]; others even reported an absence of the depinning stage on rough surfaces [117]. On the other hand, the absence of depinning stage is also observed on some extremely smooth surfaces [117, 119]. Hence Lin et al. studied the pinning and depinning dynamics on surfaces with various roughness. It was concluded that the pinning is encouraged by roughness, due to an increasing energy barrier on the surface. With increasing roughness, eventually an absence of the depinning stage can be observed on

rough surfaces [116].

5.2.3 Experiment Setup

5.2.3.1 Material

Five types of stainless steel were studied: 304, 316, 416, 420 and 420S29. Although there are 17 types of medical grade steels stated in relevant British Standards [42] for instrument manufacturing, the standards have not been updated for more than 10 years. With the development of steel manufacturing, instrument manufacturing is not limited to the 17 steel types. Stainless steel 416 used in this experiment is not listed in the British Standards. Nevertheless it is commonly used in instrument manufacturing. Being very similar to stainless steel 410 (equivalent to type A in British Standard), slightly more Sulphur is added to achieve better machinability. Equivalents of the other four steel types can be found in BS ISO 5194 [42] and are listed in Table 5.4. Stainless steel 304 is equivalent to type M, which is preferably used to manufacture retractors; Stainless steel 316, known as the steel for surgical implants, corresponds to type P; Stainless steel 420 and 420S29 are equivalent to type D and type B respectively, both types are used in many aspects such as scissors, knives, chisels and curettes. The chemical compositions of all five types were obtained from the suppliers (Bolton Surgical：Sheffield, UK; Surgical Holdings：Essex, UK) and are shown in Table 5.4. Samples were cut from flat sheets and each sample had a dimension of 30x30mm.

Weight (%)	Equivalence in BS ISO 5194	C	P	S	Si	Cr	Mn	Ni
304	M	0.26	0.031	0.001	0.40	18.12	1.74	8.01
316	P	0.07	0.046	0.006	0.64	19.31	1.91	7.93
416	~A	0.13	0.024	0.006	0.43	15.74	0.36	0.06
420	D	0.42	0.200	0.007	0.29	13.69	0.33	0.08
420S29	B	0.20	0.014	0.004	0.51	13.30	0.48	0.09

Table 5.4 Chemical compositions of stainless steels

Six surface finishes were applied to each type of stainless steel. These were representative of the types used commercially. Surface finishes applied can be divided into three main categories depending on different finishing processes: mirror, satin, and matt.

Mirror polish brightens the steel's appearance by burnishing it with a soft mop, using a suitable polishing compound. Different coloured polishing compounds provide surfaces with different roughness. (Compound colour is consistent across the market).

The process of satin finish is very similar to mirror polish as a polishing mop is used. However the mop used is harder, usually made from nylon and no compound is needed. The surface roughness is therefore governed by the mop used and not by the compound. Compared with mirror polish, the satin finish is dull but with similar morphology.

Matt finish is also dull and is achieved by bead blasting. Instead of a mop being used, spherical glass beads are blasted onto the surface using compressed air. Different grades of roughness can be achieved using different sizes of beads.

In this work, 3 types of mirror finish, 1 satin and 2 matt were prepared. The mirror finishes were produced using green, grey and pink compounds respectively; satin finish using a fine nylon mop; and the matt finishes using soda lime glass beads, commercially available type Bol27 and Bol25. Bol27 contains glass beads with a diameter between 53 and 105 μm, while Bol25 contains glass beads between 105 and 210 μm.

The surface morphology and the roughness parameter were categorised using 3D Optical Profiler (Zygo: Middlefield, USA). The size of each scanned area was 1.41 x 1.06mm under 5x magnification. Resulting roughness parameters were used as a parameter of all other measurement results, such as contact angle, vaporization time length and corrosion resistance.

It can be seen from Figure 5.12 that surfaces with mirror polish and satin finishes are characterised by directional grooves while surfaces with matt finishes are characterised by indentations. Surfaces produced by the green mirror polish compound have the smallest roughness while surfaces blasted by Bol25 the greatest. Details of the roughness (Ra) are shown in Table 5.5. All results are the mean 10 readings.

All samples were duplicated and one of each was passivated. This passivation process was finished in nitric acid for 40 minutes.

To summarise, 5 types of material were given 6 different surface finishes and duplicate samples were passivated and left unpassivated – 60 samples in total. Samples

were identified by material, finishing grade and passivation status. For example, stainless steel grade 304 mirror-polished by coloured green compound and without passivation is named as 304-Green-np; stainless steel grade 420 finished by Bol27 and with passivation is named as 420-Bol27-p.

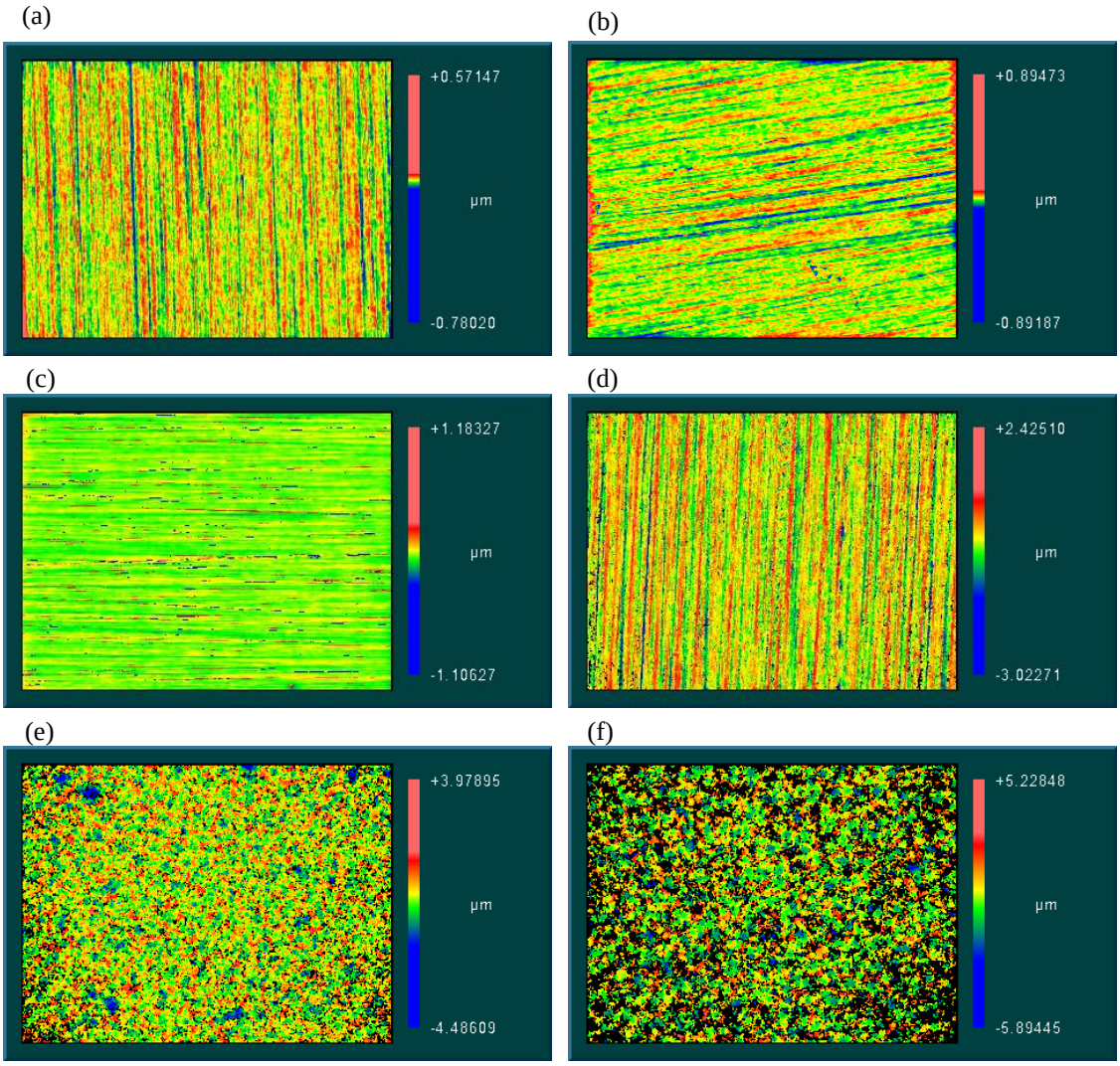


Figure 5.12 Surface morphology produced by different finishing techniques
(a) Polish-Green; (b) Polish-Grey; (c) Polish-Pink; (d) Satin; (e) Bol27 (f) Bol25

Ra(nm)	304	316	416	420	420S29
Green	5.38±0.24	4.64±0.22	8.89±0.49	13.57±0.45	10.97±0.73
Grey	13.78±0.67	10.69±0.65	10.18±0.91	16.14±0.79	14.84±0.51
Pink	22.19±1.07	18.63±0.70	19.33±1.55	23.79±0.69	21.04±1.91
Satin	296.51±11.73	283.19±6.77	342.44±14.5	258.13±23.58	289.39±9.96
Bol27	459.68±24.95	529.55±31.43	477.11±36.45	564.33±31.26	428.07±19.46
Bol25	622.13±35.42	606.34±15.76	739.63±30.78	641.57±18.25	787.75±17.99

Table 5.5 Roughness (Ra) of samples

5.2.3.2 Methods

All experiments were carried out both before and after the 150 disinfection cycles under exactly the same conditions. The disinfection cycle and the detergent used are identical to those used in section 5.2.

To study the changes in wettability, a Theta Lite Optical Tensiometer (Biolin Scientific: Esbo, Finland) was used to take images of the three-phase system and to measure the contact angle in real-time. Details of sample preparation and measurement followed the literature described in section 5.2.1.3, to maintain the consistency of the experiment set up and to minimise the error brought by the system.

To avoid the use of aggressive cleaning solutions, acetone was chosen as it has a neutral pH value. Prior to measurements, all samples were ultrasonically cleaned in acetone (Sigma Aldrich: Dorset, UK) and then in deionised water for 5 minutes each. As mentioned in section 5.2.1.3 that rubbing sample surfaces leads to highly dispersed results, samples were then dried in air without rubbing.

All measurements were made at room temperature. Deionised water was dropped on the sample surfaces and readings were made 20 seconds after the drop. Each water drop was 15 μl, as it is very close to a natural drop of water (20 μl) but can just fit into the view of the camera. It is large enough compared to surface's roughness scale, and hence enough energy was supplied to attain a GEM state. For samples with mirror-polished and satin finishes, samples were positioned so that the viewing direction of the camera was perpendicular to the surface grooves.

The experiment was repeated on each sample 5 times, where each water droplet was placed at random on the sample. The mean value was then calculated.

It is noted that although all the temperatures are checked by independent sensors in each chamber, the sensors are located just beside the air outlet at the corner and hence rather far away from the instruments. It is reasonable to suspect that the temperature near the instruments is lower than 110°C. To obtain the actual temperature inside the chamber near the instruments, another independent sensor Rotronic HL-NT3 (Rotronic: Crawley, UK) was put in the instrument tray and the readings were recorded. Recorded temperatures of one drying cycle are illustrated below in Figure 5.13. It can be seen that the temperature in the chamber was less than 60°C at the beginning and it continued to

rise during the process, the temperature inside the trays did not reach 110°C at process end. To study the evaporation mechanism of each surface, 70°C was selected as it is the mid temperature throughout the drying process.

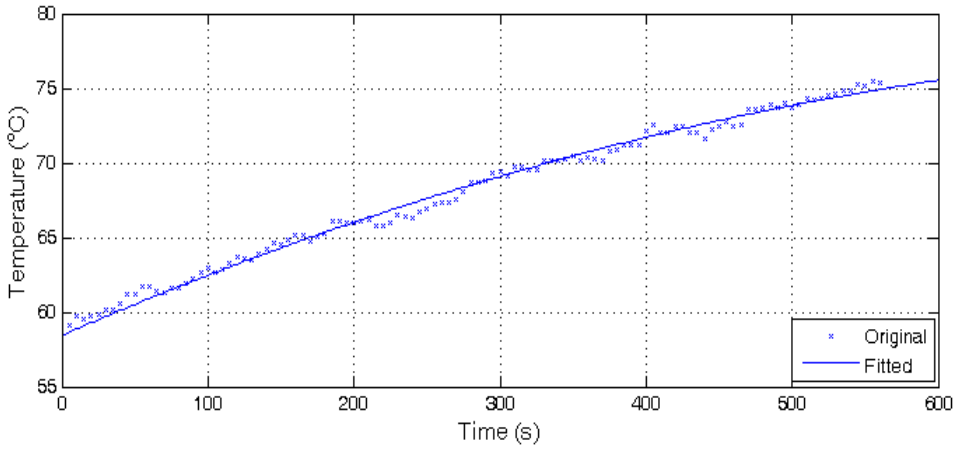


Figure 5.13 Change of temperature recorded in the instrument tray during drying cycle

The Theta Lite Optical Tensiometer was also used to monitor the behaviour of water droplets during evaporation mechanism. To maintain the temperature at 70°C, a Proportional-Integral-Derivative (PID) controlled heating stage was fabricated to control the sample temperature without affecting the tensiometer.

The PID controller is a closed-loop control system which uses the concept of an open loop system but has one or more feedback loops between its output and input. The PID controlled heating stage fabricated for the study comprises of a thermal K-type sensor, a MAX6675 module, an Arduino board, a Metal-Oxide-Semiconductor Field-Effect Transistor (MOSFET), a thin film heater and a non-thermally conductive block.

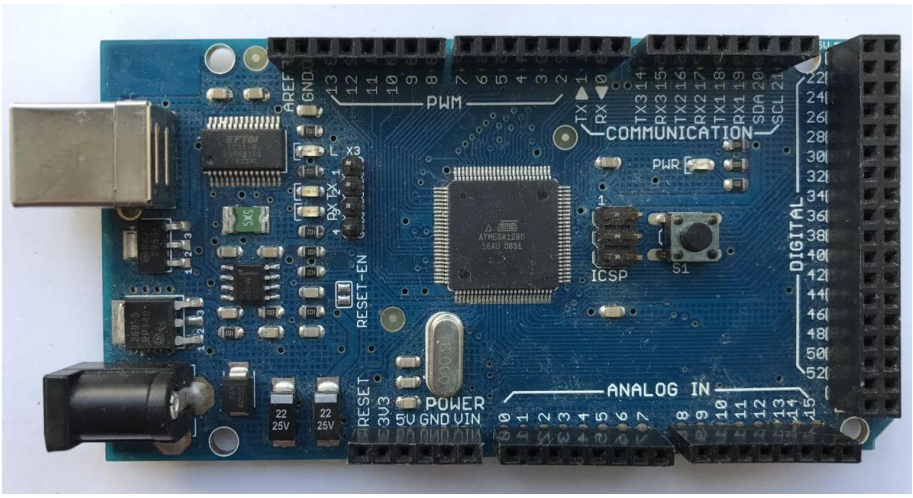


Figure 5.14 Arduino Due module

The Arduino Due module (Arduino: Ivrea, Italy) is used as the microcontroller unit (MCU), as shown in Figure 5.14. It is based on the Atmel SAM3X8E ARM Cortex-M3 CPU (Atmel: San Jose, USA) and is the first Arduino board based on a 32-bit ARM core microcontroller. The heating element used is KHLV-102/5-P (Omega Engineering: Stamford, USA), a thin film insulated heater. The size of the heating film is 3 x 5 cm and its heating power 0.78 W/cm^2 (5W/in^2) at 28V. The maximum operating temperature of the film is 232°C. The MOSFET used is D45VH10G (ON Semiconductor: Phoenix, USA), a PNP bipolar junction transistor which is current regulated to control the heating power. The K-type thermometer and the MAX6675 module (Adafruit: New York, USA) were used to monitor the temperature on the heating surface. The module communicates with Arduino Due module via MAX6675 Arduino library [120].

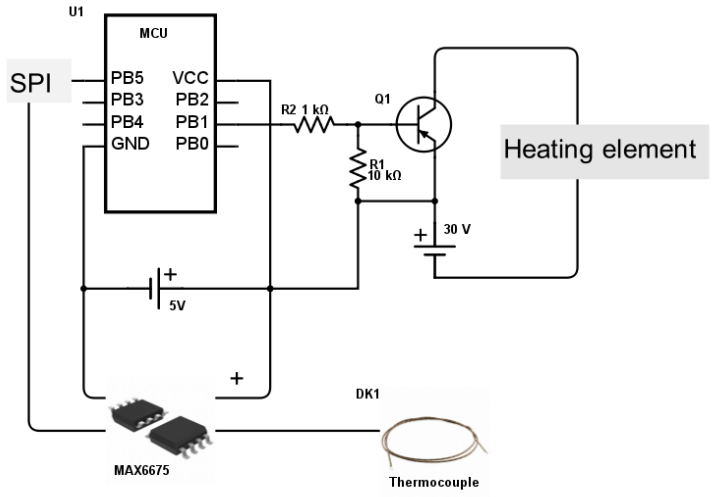


Figure 5.15 Designed circuit of the heating system

The circuit designed for the heating system is shown in Figure 5.15. It can be seen that two external power supplies are used for the setup. A constant voltage source at 5V supplies power for the Arduino module and the MAX6675 module. The other voltage source is set to 30V to provide power for the heating element. After the temperature is read from the thermocouple via MAX6675 module, this data is then transferred to MCU and processed using a PID library [121].

To protect the Arduino module from over current and to ensure that no current flows from MOSFET to output port of the Arduino (PB1), 2 resistors are added to the circuit. From the datasheets the minimum amplification factor (hFE) value of the

MOSFET is 20 and the maximum current in the heating circuit is 0.5A. The value of R2 is hence calculated as follows:

$$R2 = \text{Supply Voltage} / (\text{Maximum Current} / \text{Minimum HFE} \times 1.3) \quad (5.7)$$
$$= 30/ (0.5/20 \times 1.3)$$
$$= 923.07\ (\Omega)$$

Therefore, the value of R2 is calculated to be 923 Ω and a 1kΩ resistor was chosen for convenience. The value of R1 is typically 10 times of the value of resistor R2, hence, in this case, 10kΩ.

The heating film is attached to a thermally non-conductive block, protecting the sample stage of the tensiometer. A clamp is used on one side of the heating element to ensure the thermocouple is properly attached to the samples. (Figure 5.16) The PID controlled system is shown in *situ* in Figure 5.17.

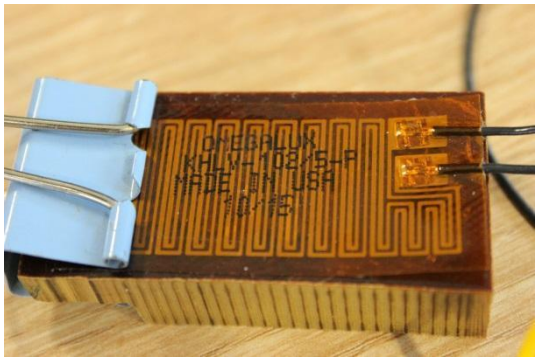


Figure 5.16 Heating film attached to thermally non-conductive block

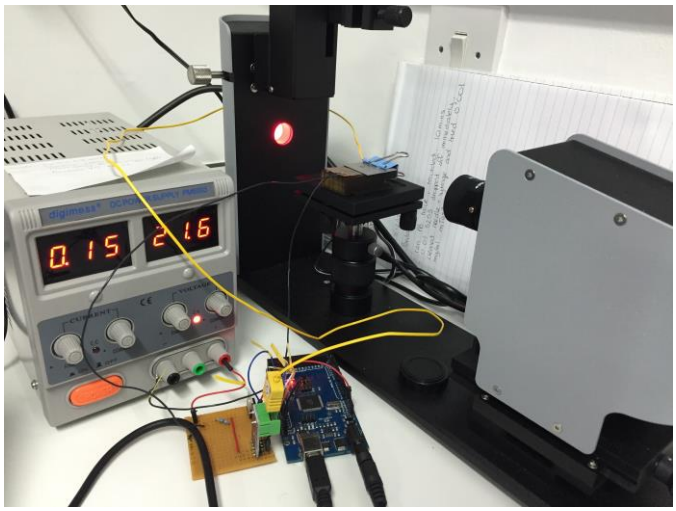


Figure 5.17 Assembled PID controlled heating system

As stated, the experiment was repeated on each sample 5 times, with a water

droplet placed at random on the sample. Images were taken every 5 seconds and the baseline length, dynamic contact angle and the volume of the droplet were recorded. The total length of time for water evaporation, from droplet placement to complete disappearance under microscope, was recorded as well.

As in the initial experiment, the depth profile analysis was performed on GD-OES with identical power and pressure settings (50W and 850Pa). A small crater was left on the sample after each measurement, making the sample unsuitable for further experiments. Therefore, the depth profile analysis was carried out last.

5.3 Results and Discussion

5.3.1 Wettability

The contact angle of each sample was measured 5 times and the results are listed in Table 5.6. Samples were categorised into 4 sets: np-nw, p-nw, np-pw and p-pw respectively. ‘np’ and ‘p’ represent the passivation state of the samples, where ‘np’ is without passivation and ‘p’ with passivation. Similarly, ‘nw’ and ‘pw’ indicates if the samples have been treated by disinfection processes or not. ‘nw’ stands for ‘not washed’ and ‘pw’ stands for ‘post wash’.

From Figure 5.18, it can be seen that regardless of treatment applied, the range of the results from different materials overlap. For example, the results of sample set np-pw range between 75° to 85° and this applies to all materials. The trends and changes on each material are similar. As a result, the performances of the material types are not differentiated. This is possibly due to the general similarity among all stainless steels chemical compositions.

Therefore, the interpretation of the results is mainly made by taking 304 as an example. Figure 5.19 shows the contact angle result of 304, illustrating the effect of roughness, passivation and disinfection processes on one material, while results of the other four materials are shown in Figure 5.20 for reference.

Contact angle (°)		np-nw	p-nw	np-pw	p-pw
304	Green	102.27±0.66	84.60±1.00	79.38±1.05	79.24±1.06
	Grey	98.86±0.66	85.08±0.48	76.12±0.95	79.71±0.87
	Pink	100.07±0.62	85.75±0.79	76.05±1.09	79.54±1.35
	Satin	83.45±0.93	84.17±0.58	80.62±1.01	79.03±0.99
	Bol27	76.59±1.31	85.56±0.49	80.88±1.12	80.46±1.47
	Bol25	88.50±0.64	88.31±1.40	84.47±1.26	82.72±1.33
316	Green	99.76±0.48	87.58±0.39	76.58±1.47	76.75±1.05
	Grey	102.77±0.24	90.01±0.52	78.57±1.54	78.48±1.35
	Pink	102.91±0.24	88.86±0.73	79.43±0.98	77.37±1.52
	Satin	80.60±1.04	87.14±0.72	79.92±1.41	76.94±1.51
	Bol27	81.77±0.49	86.07±1.03	79.48±1.38	74.38±0.69
	Bol25	89.97±0.63	89.50±1.01	82.68±0.67	78.45±1.83
416	Green	99.77±0.89	90.52±0.57	79.44±0.90	80.61±0.92
	Grey	98.72±0.57	89.21±1.01	78.01±0.79	80.21±0.71
	Pink	98.81±0.51	89.66±0.91	77.58±0.98	80.85±1.02
	Satin	74.53±0.71	88.77±1.35	77.75±1.71	81.37±0.72
	Bol27	70.41±1.39	88.88±1.08	78.91±1.09	81.37±1.32
	Bol25	83.80±0.86	87.80±0.57	85.85±0.28	86.01±1.73
420	Green	98.61±0.66	88.35±0.31	75.55±0.85	79.48±1.22
	Grey	100.79±0.44	91.22±0.48	78.25±0.76	81.58±0.38
	Pink	99.87±0.56	93.04±0.34	77.05±0.85	81.70±0.64
	Satin	80.18±0.29	91.34±1.20	77.18±0.51	85.25±0.61
	Bol27	70.60±1.37	88.02±0.40	81.24±1.24	78.87±0.95
	Bol25	88.42±0.81	87.77±0.22	83.59±0.89	79.23±1.41
420S29	Green	100.49±0.97	87.51±0.23	74.01±0.79	80.10±1.02
	Grey	100.31±0.38	90.48±0.19	76.55±0.39	81.75±0.99
	Pink	100.09±0.60	89.86±0.76	75.89±0.65	81.50±1.40
	Satin	79.40±0.96	87.04±0.66	81.01±0.71	79.46±1.54
	Bol27	73.64±1.29	86.75±0.75	81.42±1.01	79.86±1.06
	Bol25	77.27±0.71	84.08±0.76	84.32±0.66	81.59±1.01

Table 5.6 Contact angles of all samples, with various material types, surface finishes and treatments

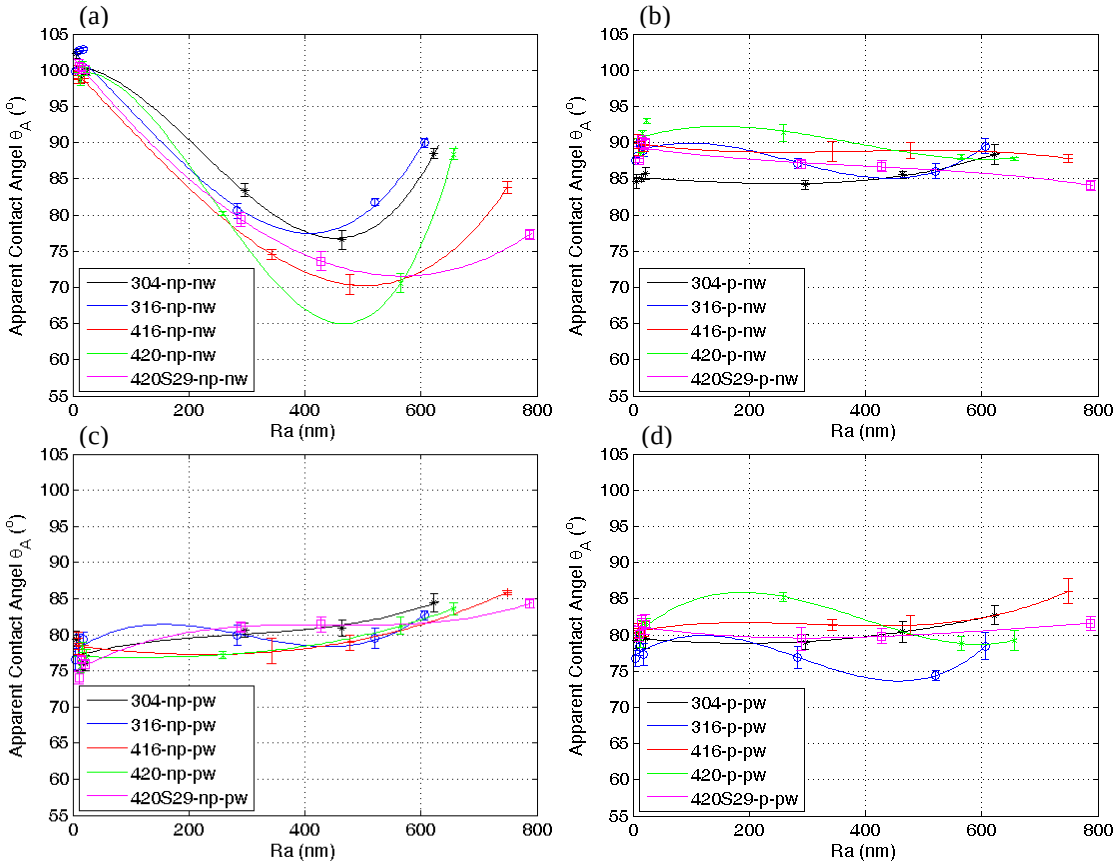


Figure 5.18 Contact angles of all samples against roughness. Each plot contains samples with all material types under the same treatment. (a) np-nw; (b) p-nw; (c) np-pw; (d) p-pw

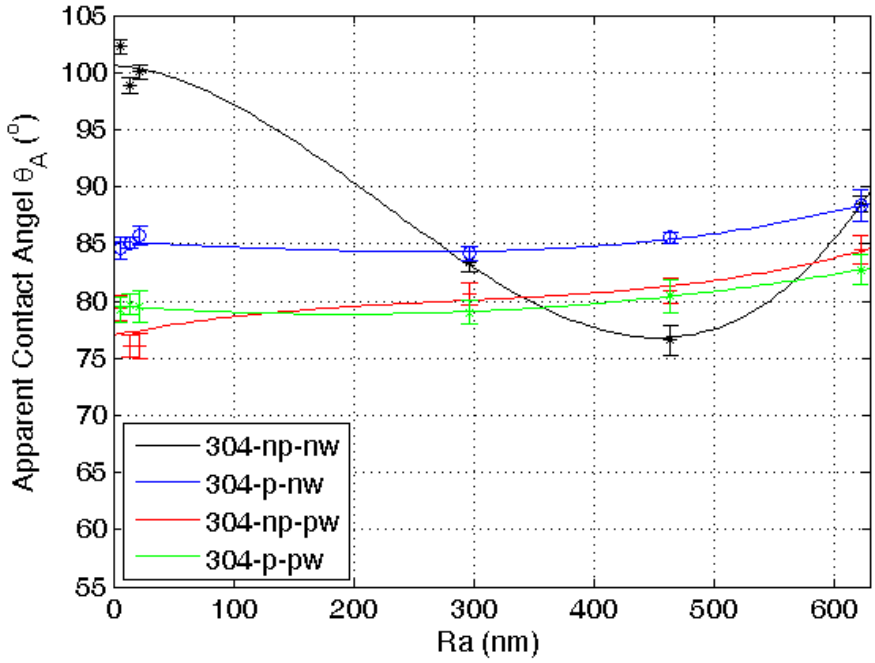


Figure 5.19 Contact angles measured on 304 samples against roughness, each line represents a sample set.

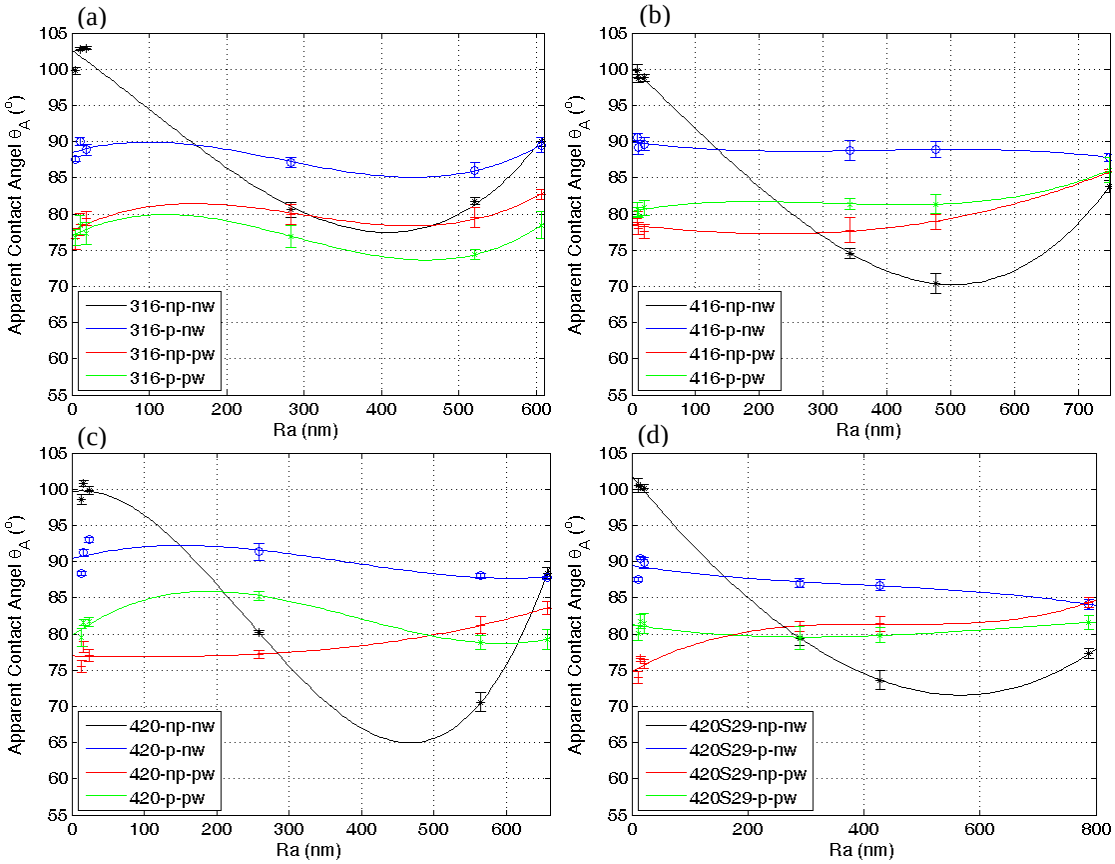


Figure 5.20 Contact angles measured on other materials against roughness, each line represents a sample set. (a) 316; (b) 416; (c) 420; (d) 420S29

5.3.1.1 Results of non-Passivated Unwashed Samples

np-nw samples are the surfaces not treated by either passivation or disinfection processes. As a result, the results of np-nw samples only reflect the influence of inherent factors of the surface: roughness.

The roughness range studied in this experiment is quite broad, from 5nm to around 800nm. However, the roughness of the 6 surface finish types is not distributed evenly. The difference between the three mirror-polished surfaces (Green, Grey and Pink) is small compared to other finishes. Even the roughest mirror-polished sample surface has a roughness of less than 25nm. To gain an understanding of the surface properties at all roughness scales, the results of mirror-polished samples are compared with each other first before discussion of other surface finishes.

It is noted in Figure 5.19 that although measured contact angles of 304-np-nw samples have a broad range (from 76° to 102°), the wettability of the three mirror-polished samples (304-Green-np-nw, 304-Grey-np-nw and 304-Pink-np-nw) is similar, at around 100°. The differences are within 4°. There are two possible reasons

for this. As mentioned above, there is a close similarity between all mirror-polished surfaces. The roughness values are not only very alike but also very small. The biggest roughness difference within one type of material lies with stainless steel 304, where 304-Pink is only around 17nm rougher than 304-Green. According to Busscher [107], the wettability difference of engineering surfaces with a roughness of under 100nm cannot be distinguished. Morphologically, all mirror-polished surfaces are characterised by directional grooves. Accordingly, water droplets perform in a similar manner. Taking into consideration these factors mentioned it is not surprising that no significant wettability difference is observed among mirror-polished samples.

On the other hand, comparing the mirror-polished samples with other finishes, the significant influence of roughness can be seen. Within the studied roughness range, there is a minimum contact angle observed with the contact angles bigger at both lesser and greater roughness, at around 450nm for 304 samples. To apply this finding to other materials, it can be seen that although the lowest value of contact angle measured is material sensitive, all lie within the roughness range of 400 to 500nm. It is observed that two surface finishes usually provide roughness at the nearest Wenzel state, Satin and Bol27.

This phenomenon with a minimum contact angle measured was also observed by Johnson [100] and Kubiak [102]. Johnson's experiment was performed on wax substrate while Kubiak's study covered a range of materials, including one specific type of steel alloy (AISI 8630). Both studies concluded that the curve trend is a result of the transition between Wenzel and Cassie-Baxter state, which is independent of materials but related to surface roughness.

From Figure 5.19, the contact angles firstly decrease with increasing roughness. This is believed to be a transition from the Cassie-Baxter state to the Wenzel state. Due to most real world surfaces behaving in an intermediate manner, such a transition is in essence a transition from the Cassie-Baxter dominant behaviour to the Wenzel dominant behaviour. With the Wenzel state gradually governing the droplet behaviour, the contact angle decreases with increasing roughness. The minimum contact angle is observed at the closest Wenzel state within the range. However, with increasing of roughness, the water droplet starts to transit from the Wenzel state back to Cassie-Baxter state. Air trapped beneath the droplet increases the contact angle and hence rougher surfaces have

a poorer wettability. It is noted that the contact angle measured on the roughest surface within the studied range was still less than 90°. This indicates that the droplet behaviour is still far from a near-Cassie-Baxter state.

5.3.1.2 Effect Brought by Passivation and Disinfection Processes

p-nw, np-pw and p-pw samples are the surfaces treated by one or both treatments: passivation and disinfection processes. In addition to inherent factors existing in np-nw samples, these three sets introduce the effect of the above treatments.

Similarity between mirror-polished samples is observed within the three sets as well. Although the contact angle value measured for each set varies, the wettability of the three mirror-polished samples remains close to each other.

Compared to 304-np-nw samples, the other three sample sets (304-p-nw, 304-np-pw and 304-p-pw) showed a markedly different distribution of contact angles. This indicates that the changes brought by passivation and disinfection processes are significant. Interestingly, the effects brought by the two treatments are similar. One is that unlike the 304-np-nw samples' wide-ranging contact angles, the disparity between samples is much smaller. The biggest contact angle measured on 304-p-nw samples is 88° while the smallest 84°, with only 4° difference. The other is that the effect brought by roughness becomes unclear, indicated by the disappearance of minimum contact angles observed in 304-np-nw sample set. This means that roughness no longer holds a dominant position above other factors.

It is proposed to be the result of a wetting behaviour changed to an intermediate state between Wenzel and Cassie-Baxter. A similar wetting mechanism eliminates the influence of roughness, giving a similar apparent contact angle on samples with various finishes. The intermediate state adds a portion of Wenzel behaviour into the mirror-polished samples, neutralising the enlarged effect of the Cassie-Baxter state and reducing the apparent contact angle. The intermediate state also affects the middle roughness range by replacing a portion of the Wenzel state with the Cassie-Baxter state, resulting in an increase of contact angle.

The blue line in Figure 5.19 shows the contact angle of 304-p-nw samples against roughness. It can be seen that all 304-p-nw samples have a contact angle range of

between 84° and 89°, regardless of their roughness variations and wettability differences prior passivation. Compared to 304-np-nw samples, the contact angles measured on 304-p-nw samples do not change as greatly with roughness. Therefore, because of the wide range of 304-np-nw results (from 76° to 102°) and the narrower range of 304-p-nw results, there exists two “crossing points” where the contact angle of 304-p-nw meets that of 304-np-nw on the graph. One is at the roughness of 300nm and the other is at 620nm.

The crossing point indicates the roughness whose wettability remains the same after passivation. Although, here, the roughness of the two crossing points happen to be the roughness of 304-Satin and 304-Bol25, this is not always the case for other materials. The first crossing point observed for all the other materials is at around 150nm, which is smoother than Satin finish. The roughness of the second crossing point varies greatly, some not even within the studied range, but its presence can be predicted at the roughness before or around 800nm.

As mentioned in section 5.3.1.1, 400 to 500nm is the roughness range believed to be the near-Wenzel state in np-nw samples, hence the roughness before and after this range are all considered to behave in intermediate states with different portions of Wenzel and Cassie-Baxter state. It is believed that the crossing points happen to be the roughness where their wetting mechanism behaves in an intermediate manner prior passivation and barely changes through passivation.

Comparing the trend of blue line and red line in Figure 5.19 indicates that the changes brought by disinfection processes are similar to the passivation treatment but more significant. Compared to 304-p-nw samples, the contact angles measured on 304-np-pw samples are smaller. The differences between 304-p-nw and 304-np-pw sets at each roughness are similar, between 5° and 10°. The smallest observed is 76° (304-Pink-np-pw) and the largest is 84° (304-Bol25-np-pw). Two crossing points that meet the results of 304-np-nw are also observed within the studied range. One is at 340nm and the other is at 580nm. The roughness of the two crossing points are different from material to material as well, just as in p-nw samples.

Compared to the 304-np-pw samples, the contact angle range of the 304-p-pw samples (the green line in Figure 5.19) is very similar but narrower, from 79° to 82°. Compared to 304-p-nw samples, the contact angles of 304-p-pw samples are

consistently smaller, with a difference of 5° at all studied roughness. For other materials, a similar effect is observed, a similar averaged contact angle consistent difference from p-nw samples (up to 10°).

Although the influences of passivation and disinfection processes are similar, it is noted that the effect brought by the disinfection process is more significant than passivation, especially on mirror-polished samples. The contact angles measured on mirror-polished np-pw samples are approximately 10° lower than p-nw samples. The rougher surfaces show a better wettability as well, with a decrease of about 5° in contact angle compared to p-nw samples. The p-pw set, showing the additive effect of both processes, shows a similar result to the np-pw set. This indicates that, regardless of the sample passivation state, disinfection processes can overwhelm the influence of passivation. However it is worth noticing that the disinfection processes carried out in this study mimics one year's treatment while passivation only takes 40mins.

To conclude, the differences between materials cannot be distinguished, regardless of treatments applied. Therefore, when it comes to material choosing for instrument manufacturing, its required mechanical properties should still be considered as the priority. The influence of roughness is observed on np-nw samples, however not on any other sample sets after treatment.

The effect brought by passivation and disinfection processes on wettability is huge. This is to say that the wettability of unpassivated instruments changes greatly through use. Such changes occur during use brings the uncertainty of instruments behaviour. For example, a piece of mirror-polished surgical instruments without passivation will change from hydrophobic to hydrophilic during use. Depending on the required surface property, it might not be suitable for the specific application anymore. The similarity between passivation and disinfection processes is indicated by a disappearance of roughness effect. Although the disinfection process has a more significant effect compared to passivation process, it is a mimic of a long period of time: one year. Passivation, on the other hand, only takes 40min and can brings the wettability of instruments to a near stable value prior use. The change of wettability during use would then be minimised. Where some specific instruments are impossible to be passivated, the ones finished to a roughness at or around the crossing point would have the least change in wettability during use.

5.3.2 Evaporation Mechanism

To understand the mechanism of how water droplet evaporates on different finishes, experiments were repeated on each sample 5 times. The total length of time needed for water evaporation was recorded and results are shown in Table 5.7.

While the time water droplet takes to evaporate reflects the surfaces property, the evaporation mechanism behind is the root cause. In order to have a better comprehension of the evaporation mechanism, water droplet baseline length, contact angle and volume were all recorded throughout evaporation.

Prior to discussing further, it is necessary to illustrate all three evaporation modes observed in this study. First is the CCR mode, where the contact radius remains unchanged with a continuous decreasing contact angle. Second is the CCA mode, where the contact angle stays steady while the contact radius gradually decreases. The third type is not reported in the literature. It is characterised by a continuous decrease in both contact radius and contact angle and hence named as “shrink mode”, indicating the shrinking of droplet size in all aspects.

Figure 5.21 shows the evaporation process of 416-Grey-np-nw and 416-Pink-np-nw, in which all three evaporation modes can be observed. For 416-Grey-np-nw, a discontinuity is observed between CCR mode (0s to 80s) and shrink mode (90s to 190s). Different from the CCA mode and the shrink mode where the contact radius gradually decreases, the discontinuity is characterised by a rapid decrease in contact line and is accompanied by a corresponding increase in contact angle. It is usually observed in a very short period of time (5-10s). The evaporation process of 416-Pink-np-nw is consisted of three stages, first the CCR mode (0s to 95s) then the CCA mode (95s to 155s) and last the CCR mode again (155s to 180s).

From Figure 5.22, it can be seen that the time takes to evaporate a water droplet on np-nw samples ranges from 105s to 200s and there’s no clear difference observed between materials. The similar range of measured results can be observed on other samples sets as well hence the differences between materials are not identified. Therefore, the interpretation of the results is again made on the basis of 304, including evaporation mechanism. Additional discussion is stated where 304 cannot represent the result of all other materials.

Drying time (s)		np-nw	p-nw	np-pw	p-pw
304	Green	153.84±3.71	135.06±1.81	133.03±3.53	133.12±1.20
	Grey	149.34±6.43	138.42±2.15	134.35±2.16	139.41±2.34
	Pink	144.53±6.22	145.66±3.26	134.46±2.67	144.83±2.48
	Satin	134.19±1.79	116.57±2.37	134.40±3.24	142.66±2.11
	Bol27	113.71±2.28	109.97±2.49	137.06±2.67	135.66±2.19
	Bol25	105.50±2.18	126.35±2.77	137.20±2.85	131.65±1.05
316	Green	156.05±3.85	134.98±2.29	139.58±2.13	141.03±2.30
	Grey	153.06±1.84	141.20±1.88	140.69±2.67	141.71±2.03
	Pink	145.51±1.87	144.19±2.36	142.46±2.52	142.81±1.43
	Satin	130.53±0.78	124.23±3.07	138.60±2.15	144.39±2.47
	Bol27	115.41±1.95	122.66±1.64	137.21±1.24	139.60±1.83
	Bol25	112.51±1.39	130.63±2.12	135.65±1.95	132.69±1.67
416	Green	185.17±4.15	171.42±2.20	152.26±1.47	146.65±1.11
	Grey	184.15±3.21	174.45±3.52	147.37±1.29	148.64±1.73
	Pink	182.38±2.79	180.65±5.28	144.07±1.93	147.74±2.00
	Satin	146.65±3.77	164.71±5.04	144.07±2.65	146.88±1.81
	Bol27	120.80±2.79	125.55±3.27	135.12±3.30	143.36±2.15
	Bol25	118.41±0.60	140.48±1.75	135.06±2.88	143.04±1.46
420	Green	181.41±4.96	141.33±1.84	139.87±1.30	135.73±1.54
	Grey	176.22±2.92	151.10±1.95	135.16±1.53	147.87±1.54
	Pink	158.64±5.20	163.15±2.66	136.49±1.68	153.58±1.84
	Satin	146.68±4.62	155.32±2.05	129.01±2.59	144.99±2.81
	Bol27	139.20±0.84	142.66±0.50	126.15±2.52	138.75±2.85
	Bol25	139.11±2.57	154.20±1.82	120.44±2.30	135.34±2.26
420S29	Green	197.04±0.85	155.82±5.95	139.95±2.79	157.67±2.12
	Grey	197.70±3.46	163.19±4.52	147.02±3.02	154.11±2.57
	Pink	181.33±2.02	172.86±1.19	141.49±2.24	151.51±3.00
	Satin	155.53±2.48	150.01±3.27	138.79±1.55	147.05±2.25
	Bol27	135.91±1.47	133.38±2.57	130.75±1.26	146.03±1.94
	Bol25	131.93±2.18	151.65±3.05	131.95±2.12	138.21±3.10

Table 5.7 Drying time of all samples, with various material types, surface finishes and treatments

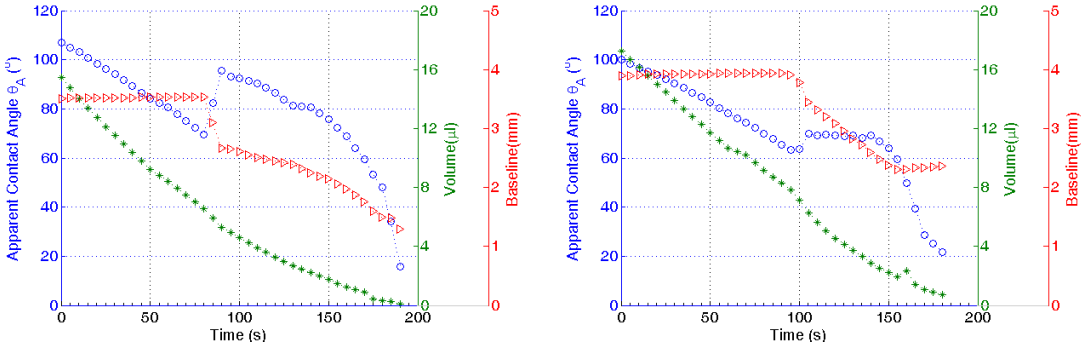


Figure 5.21 Illustration of evaporation modes; Left: 416-Grey-np-nw; Right: 416-Pink-np-nw

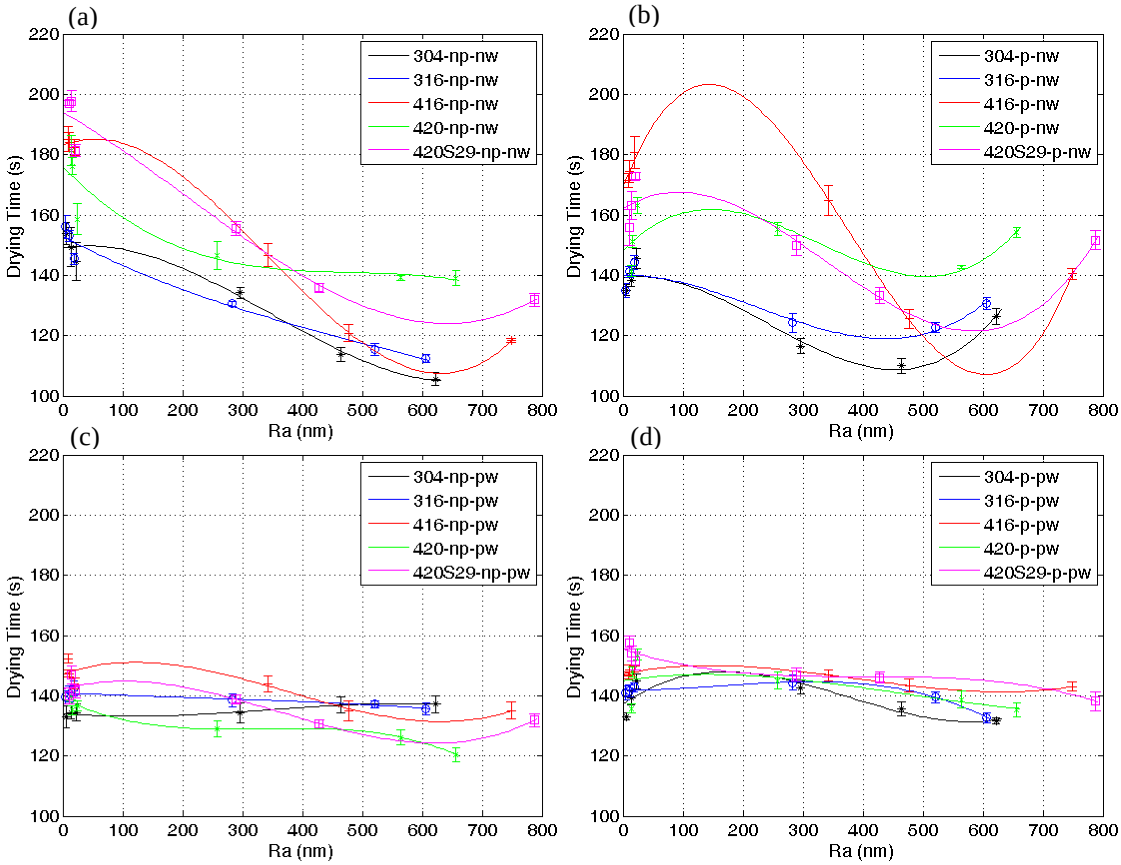


Figure 5.22 Drying time of all samples against roughness. Each plot contains samples with all material types under the same treatment. (a) np-nw; (b) p-nw; (c) np-pw; (d) p-pw

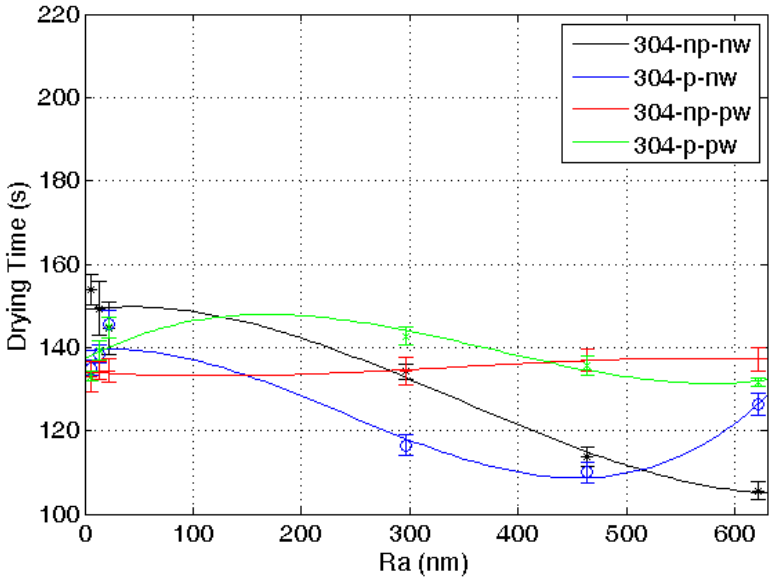


Figure 5.23 Drying time measured on 304 samples against roughness, each line represents a sample set.

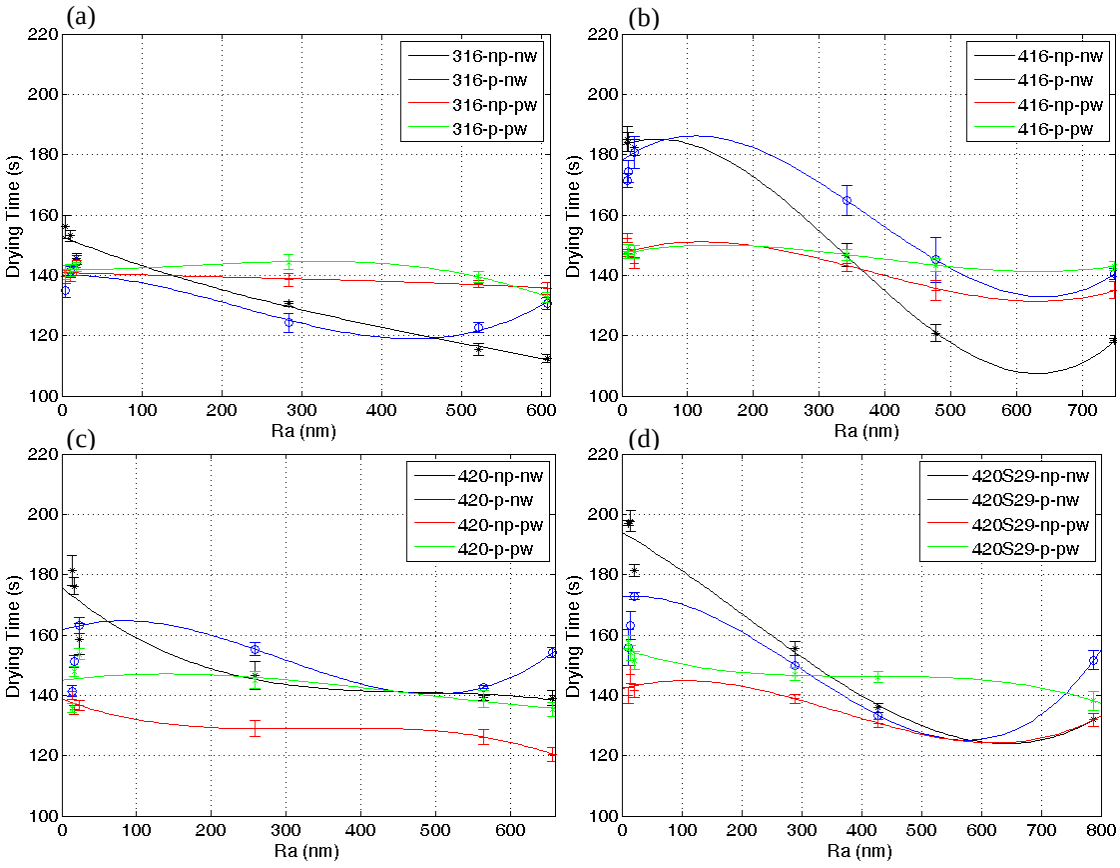


Figure 5.24 Drying time measured on other four materials against roughness, each line represents a sample set. (a) 316; (b) 416; (c) 420; (d) 420S29

Figure 5.23 illustrates the drying time differences of 304 samples against roughness between the sets treated differently. Drying time required for the other four materials with various roughness and treatments can be seen in Figure 5.24.

5.3.2.1 Results of non-Passivated Unwashed Samples

Due to the small differences between mirror-polished samples (Green, Grey and Pink), their results are compared with each other prior to being compared with other finishes.

Unlike the similarity observed in the wetting property, the evaporation time of mirror-polished 304-np-nw samples varies greatly. As seen in Table 5.7, the drying time difference between 304-Green-np-nw and 304-Pink-np-nw is around 9s while the range of the set is only 48s, between 304-Green-np-nw and 304-Bol25-np-nw. A decreasing trend with roughness is observed on all mirror-polished np-nw samples drying time, although significant only on some materials, such as 304-np-nw and 420-np-nw.

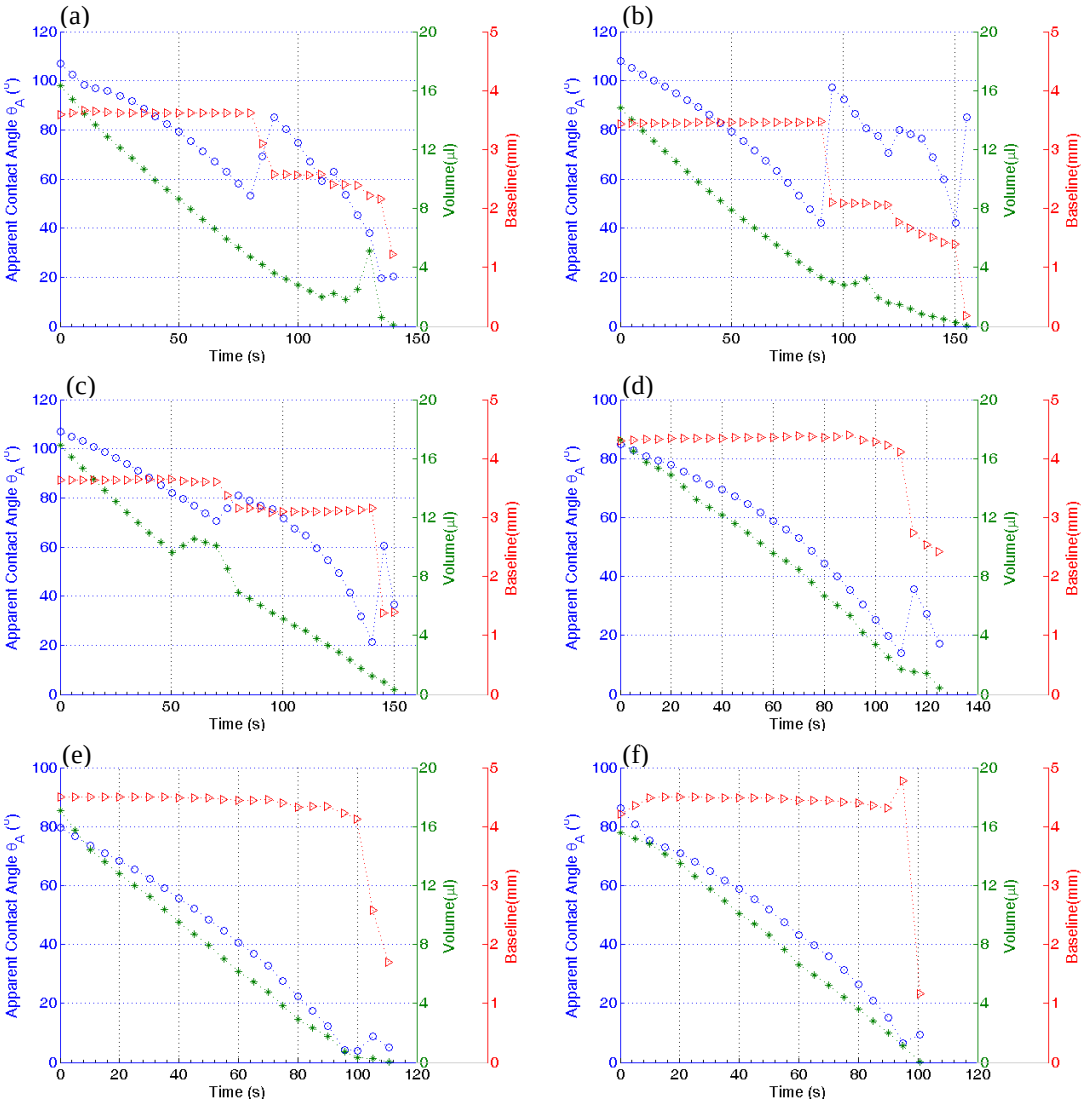


Figure 5.25 Evaporation mechanism of 304-np-nw samples
(a) Green (b) Grey (c) Pink (d) Satin (e) Bol27 (f) Bol25

The evaporation mechanism of 304 mirror-polished samples can be seen in Figure

5.25, (a) - (c). It is noted that although the latter half of evaporation process differs from each other, the evaporation all started with a CCR mode. The CCR mode of 304-Green-np-nw and 304-Grey-np-nw lasted for 80s and 90s respectively before their baseline rapidly decreases. A longer CCR mode indicates bigger contact areas hence shorter drying time. On the other hand, the CCR mode of 304-Pink-np-nw lasted for only 70s before a discontinuity. However, the baseline decrease is much smaller compared to the other two mirror-polished surfaces. The baseline was kept to a closer value in the second CCR stage and resulted in a shorter drying time.

The decreasing trend with roughness can also be explained by a gradual change of the droplet behaviour from the Cassie-Baxter manner to the Wenzel manner. As proposed in section 5.3.1.1, this transition takes place at the first half of the roughness range till around 400nm. The closer to the near-Wenzel state, more grooves and holes are filled by liquid. Thus the increasing roughness dictates a larger contact area between water droplet and the surface. As a result, the total time needed to fully evaporate a drop of water decreases with the slight increase of roughness.

While the drying time difference of 420-np-nw mirror-polished samples is as significant as 23s, disperse of mirror-polished sample results is not observed within all material set, as there is only 3s differences among mirror-polished samples of 416-np-nw set. The un-prescribed interrelationship among mirror-polished samples is believed to be the result of mixed evaporation mechanism.

While the CCR mode can be observed on all samples and the discontinuity on most ones, the CCA mode and the shrink mode appear only in some mirror-polished samples. In other words, the evaporation mechanism of mirror-polished samples usually comprises of several stages and is a combination of different modes.

Stainless steel is a typical type of high-energy surface, on which water droplets should evaporate with a pinned contact line (CCR mode). However, all mirror-polished samples are considered as smooth surfaces and hence the friction available to pin the contact line is small. This would result in the CCA mode evaporation. Therefore, the multi-stage and mix mode of evaporation on mirror-polished surfaces can be considered as a competing result from the two factors. There is a third mode observed in the experiment which has not been reported in the literature, the shrink mode. It can be interpreted as another form of CCA mode, only the evaporation is accelerated by the

heated surface. In other words, the evaporation mechanism is the CCA mode in nature, but the contact angle could not remain steady during the time period of contact radius decrease because of the rapid evaporation rate.

For example, the evaporation processes of 420S29-Green-np-nw and 420S29-Grey-np-nw illustrated in Figure 5.26 both start with CCR mode but are quite different from each other. The evaporation process of 420S29-Green-np-nw consists of two consecutive CCR modes starting at 0s and 90s, a shrink mode at 140s, another short CCR mode from 170s to 180s and finally a shrink mode till the droplet disappears. In contrast, 420S29-Grey-np-nw has only two stages, a CCR mode (0s to 100s) and a shrink mode (100s to 195s). Despite the differences in evaporation modes and stages, the resulted drying time is very similar.

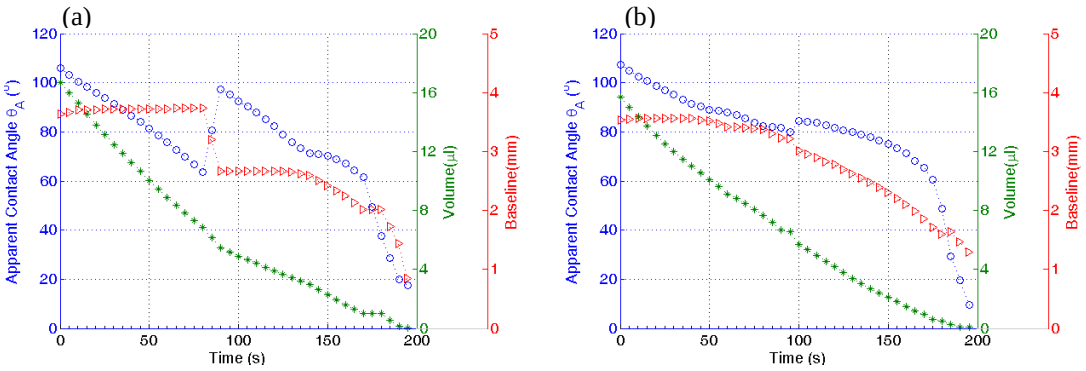


Figure 5.26 Evaporation mechanism of mirror-polished 420S29-np-nw samples. (a) Green (b) Grey

The effect of roughness is not only observed on mirror-polished samples, but also on all 304-np-nw samples with other surface finishes. Although the drying time continues to decrease with roughness, it can be seen from the black line of Figure 5.23 that the rate is not proportional to roughness. Initially, the drying time decreases rapidly with increasing roughness. This is reflected by the slope of the fitted curves. However, the slope flattens with the increase of roughness (from around 530nm) and thus the effect less marked.

This is due to the transition from the near-Wenzel state back to the Cassie-Baxter state and is observed at the roughness of around 400nm, which is the same roughness range observed in the contact angle measurement. Air trapped between the steel surface and the water droplet reduces the heat conduction and results in a longer drying time.

However, it has been impossible to define the clear border of the transition between Wenzel state and Cassie-Baxter state in this study. Since the contact angle

measurement and the evaporation process is videoed from a side view, only a projection of the droplet and surface can be seen. The detailed interface between water droplet and sample surface cannot be observed.

The evaporation mechanism differences between mirror-polished samples and others can be clearly seen as well. It is noted that with the increase of roughness, the CCR mode tends to govern a bigger portion of the whole evaporation process. Figure 5.25 shows that while the first CCR mode observed on 304-Green-np-nw only lasted for approximately half of the evaporation process (80s out of 140s), the baseline of 304-Satin-np-nw did not change until 15s before droplet disappeared, for 304-Bol27-np-nw, 10s and for 304-Bol25-np-nw, 5s.

A significant factor in the latter half of the studied range which governs the drying time is the friction due to extreme roughness. It is known that the pinning/depinning [117] is "a competition between capillary and friction forces". With increasing roughness, the friction gradually governs the evaporation mechanism. The rougher the surface, the more friction and the higher the energy barrier. It is then harder for water droplets to act against the friction force. Therefore, with the increase of surface roughness, the depinning of contact line occurs closer to the end of the drying process. Although the Wenzel portion behaviour is less on rougher surfaces, the reduced capillary effect simply cannot compete with the large friction. Increasing roughness eventually results in an absence of depinning.

The other difference between mirror-polished samples and the others is the absolute value of initial contact angle. The initial contact angles of the three mirror-polished samples, as shown in Figure 5.25 (a) to (c), are similar but relatively high, at around 110°, while the ones of other np-nw samples are all under 100°. Because the volume of the placed water droplet is set to be $15\mu l$, a higher initial contact angle indicates a smaller contact area, hence a longer drying time.

5.3.2.2 Effect Brought by Passivation and Disinfection Processes

Comparing the blue line and the black line of Figure 5.23, the results of 304-p-nw samples drying time are slightly different from 304-np-nw ones. Overall, the range of drying times is smaller. The measured drying time range of 304-p-nw is 12s smaller than 304-np-nw.

The drying time of mirror-polished samples decreased significantly. As proposed in section 5.3.1.2, a change of wetting mechanism is brought by passivation and disinfection processes. Therefore, on smooth surfaces where friction is small, the contact area between liquid and stainless steels increases due to the additional Wenzel process and results in a shorter drying time.

After passivation, the influence of roughness is still detectable. Similar to the trend of 304-np-nw samples, the drying time of the 304-p-nw samples decreases rapidly with increasing roughness initially, up to a roughness of around 400nm and then more slowly with increasing roughness. Compared to 304-np-nw samples, the difference can be seen in the increase in drying time at greater roughness, such as 304-Bol25-p-nw.

Again this can be explained by the proposed theory in section 5.3.1.2. After the roughness of 400nm which is believed to be the most near-Wenzel state within the studied range, the wetting mechanism on samples started to change back to Cassie-Baxter state. With the additional Cassie-Baxter state, the contact area between the droplet and the surface is smaller hence resulted in a longer drying time.

Figure 5.27 shows the evaporation mechanism of 304-p-nw samples with various finishes. A comparison between 304-Green-np-nw (Figure 5.25 (a)) and 304-Green-p-nw (Figure 5.27 (a)) gives a clear idea of the influences brought by passivation. An extended CCR stage is observed on 304-Green-p-nw, with its discontinuity appears at later than 75% of the process (100s out of 130s) while only around half at the process of 304-Green-np-nw.

The change in wetting behaviour also affects the evaporation mechanism of tested samples. The mirror-polished surfaces are considered to be very smooth and hence little friction exists to stop the contact line depinning. The additional Wenzel process, however, creates a capillary beneath the liquid and helps the water droplet stay pinned. The decreased drying time is the compromise of the two factors above. However with the increasing roughness, the friction governs the evaporation mechanism again and hence the drying time and evaporation mechanism are much less changed.

As a result of the extended CCR stage in mirror-polished samples and the barely changed values of other finishes, the evaporation mechanism becomes alike after treatments. In other word, the influence of roughness on the evaporation mechanism

becomes less significant after passivation.

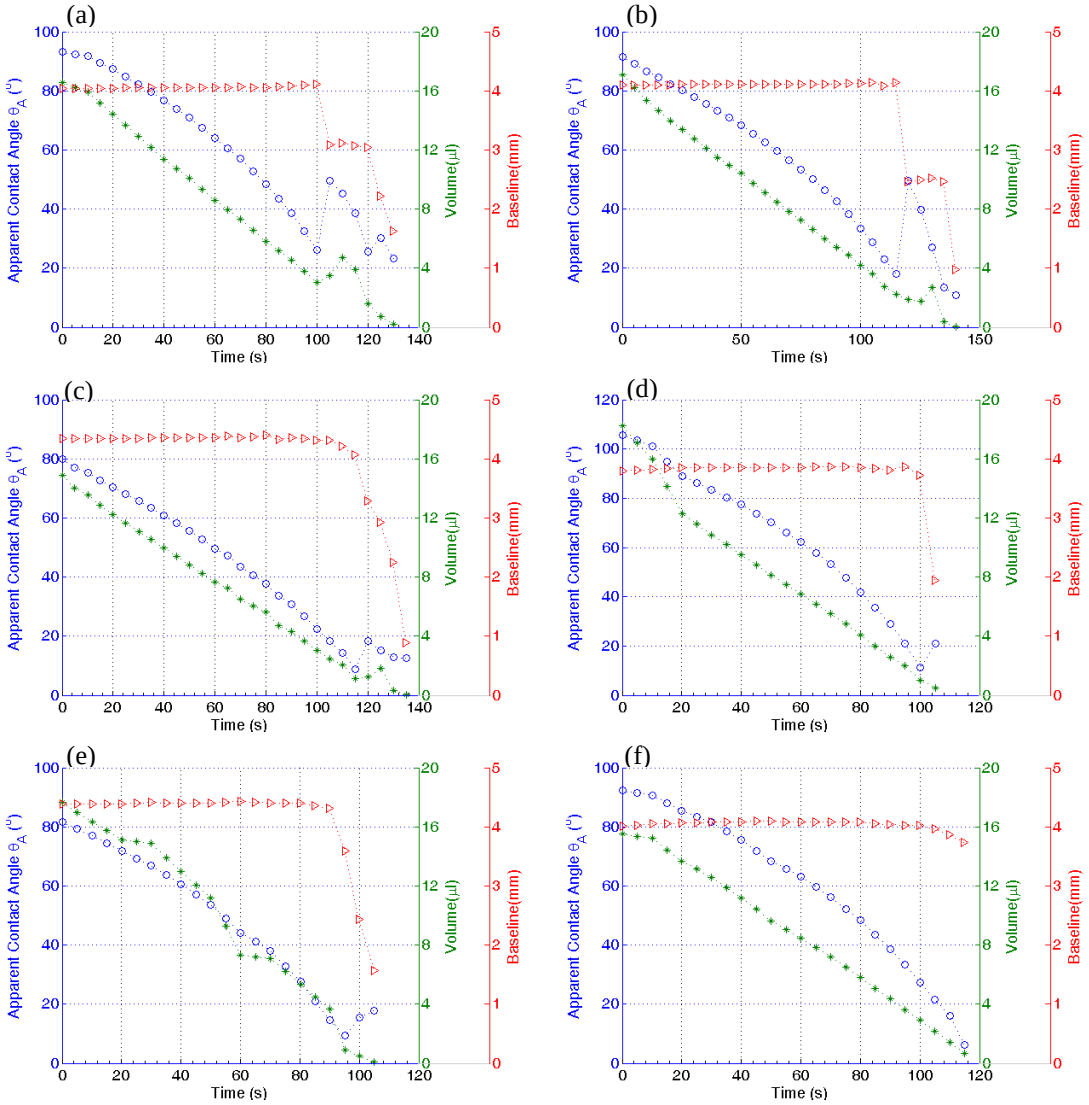


Figure 5.27 Evaporation mechanism of 304-p-nw samples

(a) Green (b) Grey (c) Pink (d) Satin (e) Bol27 (f) Bol25

The results of 304-np-pw and 304-p-pw samples appear to be very alike, however significantly different from the other two sets. Both 304-np-pw and 304-p-pw samples have a relatively narrow distribution of drying time, with an averaged drying time of around 140s and the range does not exceed 10s on either direction. Although a slight wave form is still observed in 304-p-pw (the green line in Figure 5.23), both post wash sets can be considered as free from the influence of roughness.

Figure 5.28 and Figure 5.29 show the evaporation mechanisms recorded on 304-np-pw and 304-p-pw. It is clearly seen that the effect brought by passivation and disinfection processes are similar. Similar to 304-p-nw, both mirror-polished 304-np-pw and 304-p-pw samples showed an extended CCR stage, only with even longer duration.

The discontinuity of 304-Green-np-pw is observed at 85% of the process (110s out of 130s) and 304-Green-p-pw more than 90% (120s out of 130s). Moreover, the disinfection processes does not appear to affect the evaporation mechanism of Satin, Bol27 and Bol25 samples either.

From the evaporation mechanism change in 304 mirror-polished samples after treatments, the effect of roughness is minimised and the significance of the effect ranks as: 304-np-nw > 304-p-nw > 304-np-pw > 304-p-pw. In other words, the effect brought by disinfection processes on the surfaces evaporation mechanism is more significant than by passivation.

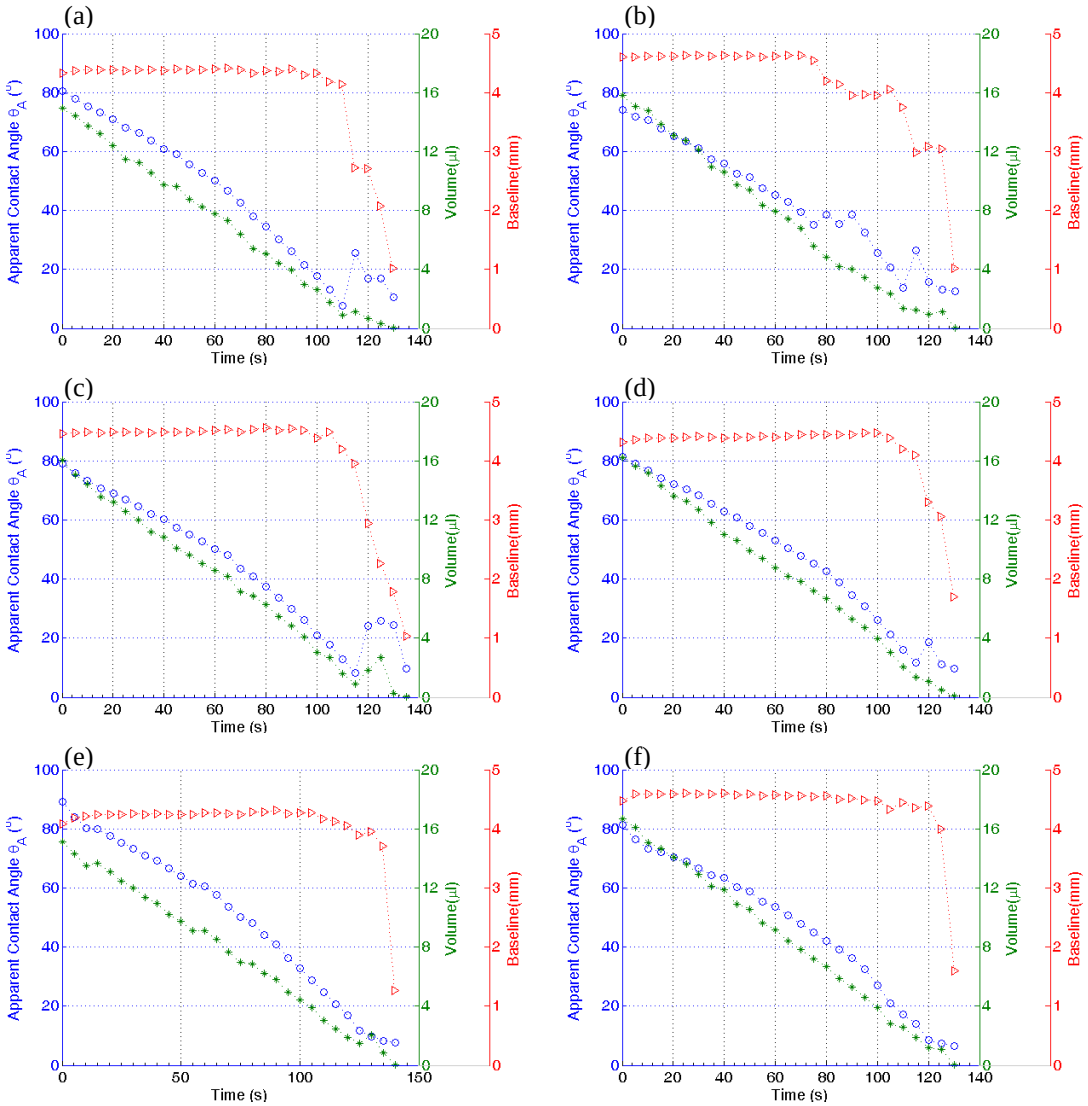


Figure 5.28 Evaporation mechanism of 304-np-pw samples

(a) Green (b) Grey (c) Pink (d) Satin (e) Bol27 (f) Bol25

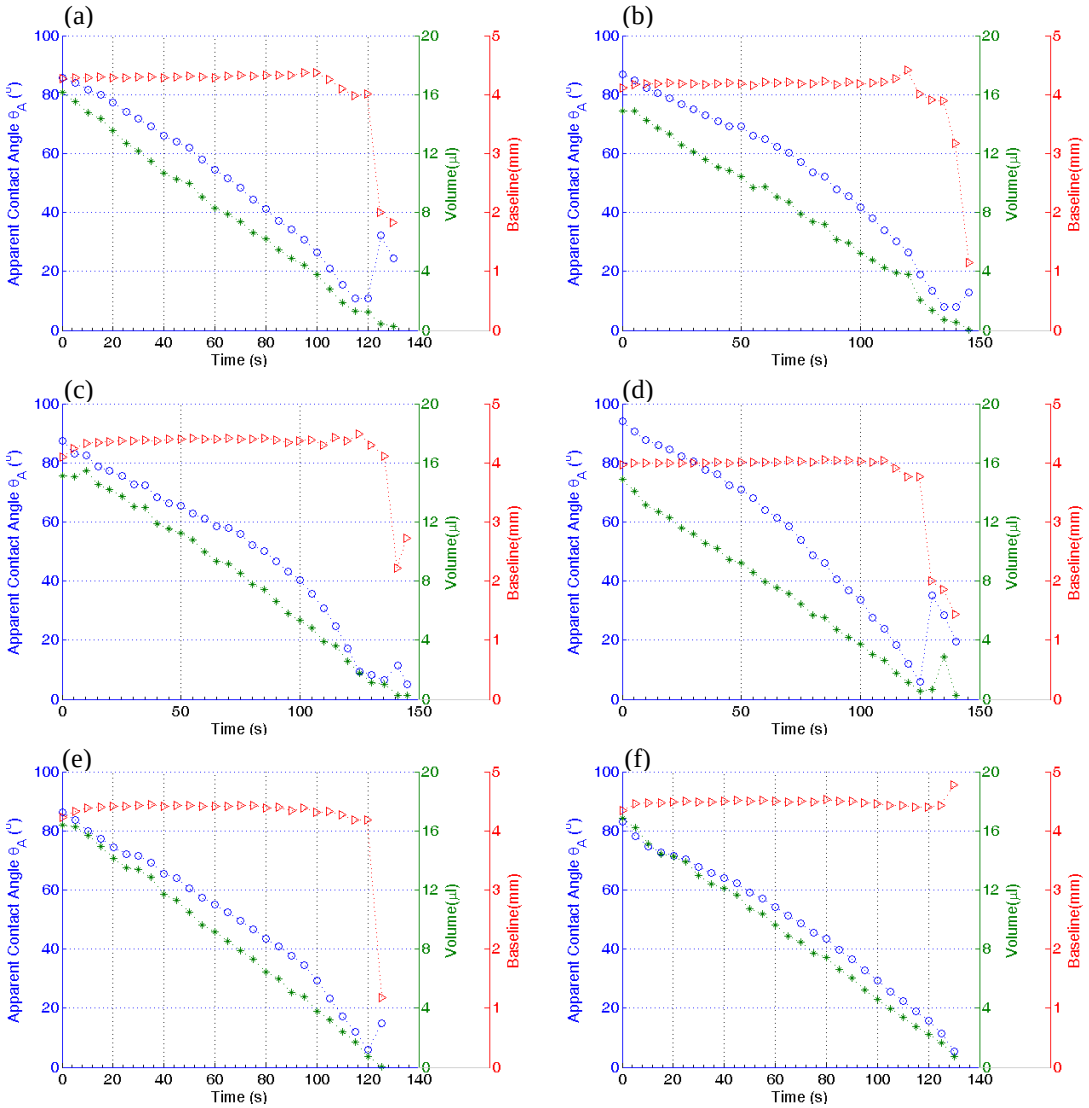


Figure 5.29 Evaporation mechanism of 304-p-pw samples
(a)Green (b) Grey (c) Pink (d) Satin (e) Bol27 (f) Bol25

To conclude, similar to the findings from wettability results, the differences between materials cannot be distinguished, regardless of treatments applied. The influence of roughness is observed on unwashed samples, with or without passivation. The smoother the surface is, the longer it takes to fully evaporation a droplet. Instruments with a roughness of around 500 to 600nm require the least drying time. It is suggested that for the applications with large flat areas, satin or reflection-reduced finishes suits more as more water are likely to be deposited and hence longer drying time would be required.

On the other hand, the effect of roughness is reduced by passivation processes and minimised by disinfection processes. Although passivation does not eliminate the effect of roughness, the changing in their evaporation mechanism is crucial by helping instruments to achieve the stable evaporation behaviour sooner.

5.3.3 Surface Profile

The detected ratio by weight (wt%) of Cr and Fe ions are converted into their atomic ratio (at%). The exact peak values of Cr/Fe (at%) are shown in Table 5.8. This section is discussed by taking stainless steel 304 as an example as well. Figure 5.30 illustrates the differences of various treatments and surface finishes. It plots the Cr/Fe value against sputtering time. The time taken to sputter gives a measure of distance from the surface. A marker is placed on each result for clearer indication of its peak position and value.

Cr/Fe	np-nw	p-nw	np-pw	p-pw	Cr/Fe	np-nw	p-nw	np-pw	p-pw
304					**316**				
Green	0.399	0.754	1.616	1.737	Green	0.406	0.841	1.232	1.489
Grey	0.264	0.329	1.448	2.000	Grey	0.261	0.830	1.321	1.354
Pink	0.213	0.257	2.109	2.015	Pink	0.245	0.620	1.004	2.298
Satin	0.207	0.438	0.516	0.525	Satin	0.221	0.277	0.448	0.575
Bol27	0.254	0.497	0.663	0.931	Bol27	0.211	0.281	0.596	0.922
Bol25	0.161	0.645	1.175	1.250	Bol25	0.155	0.317	1.554	0.782
416					**420**				
Green	0.308	0.657	0.927	1.437	Green	0.455	0.835	1.164	1.556
Grey	0.356	0.363	0.831	0.913	Grey	0.329	0.622	0.986	0.953
Pink	0.188	0.258	0.618	0.722	Pink	0.179	0.263	0.528	0.750
Satin	0.124	0.222	0.242	0.280	Satin	0.133	0.280	0.474	0.870
Bol27	-	0.160	0.280	0.325	Bol27	-	0.216	0.184	0.348
Bol25	-	0.283	0.343	0.634	Bol25	-	0.222	0.784	0.962
420S29									
Green	0.354	0.407	0.606	1.025					
Grey	0.255	0.270	0.650	1.222					
Pink	0.234	0.313	0.672	0.781					
Satin	0.127	0.464	0.418	0.606					
Bol27	0.133	0.203	0.246	0.414					
Bol25	-	0.384	0.294	0.445					

Table 5.8 Value of Cr/Fe at peak; with various material types, surface finishes and treatments.
'-' indicates no Cr/Fe peak detected

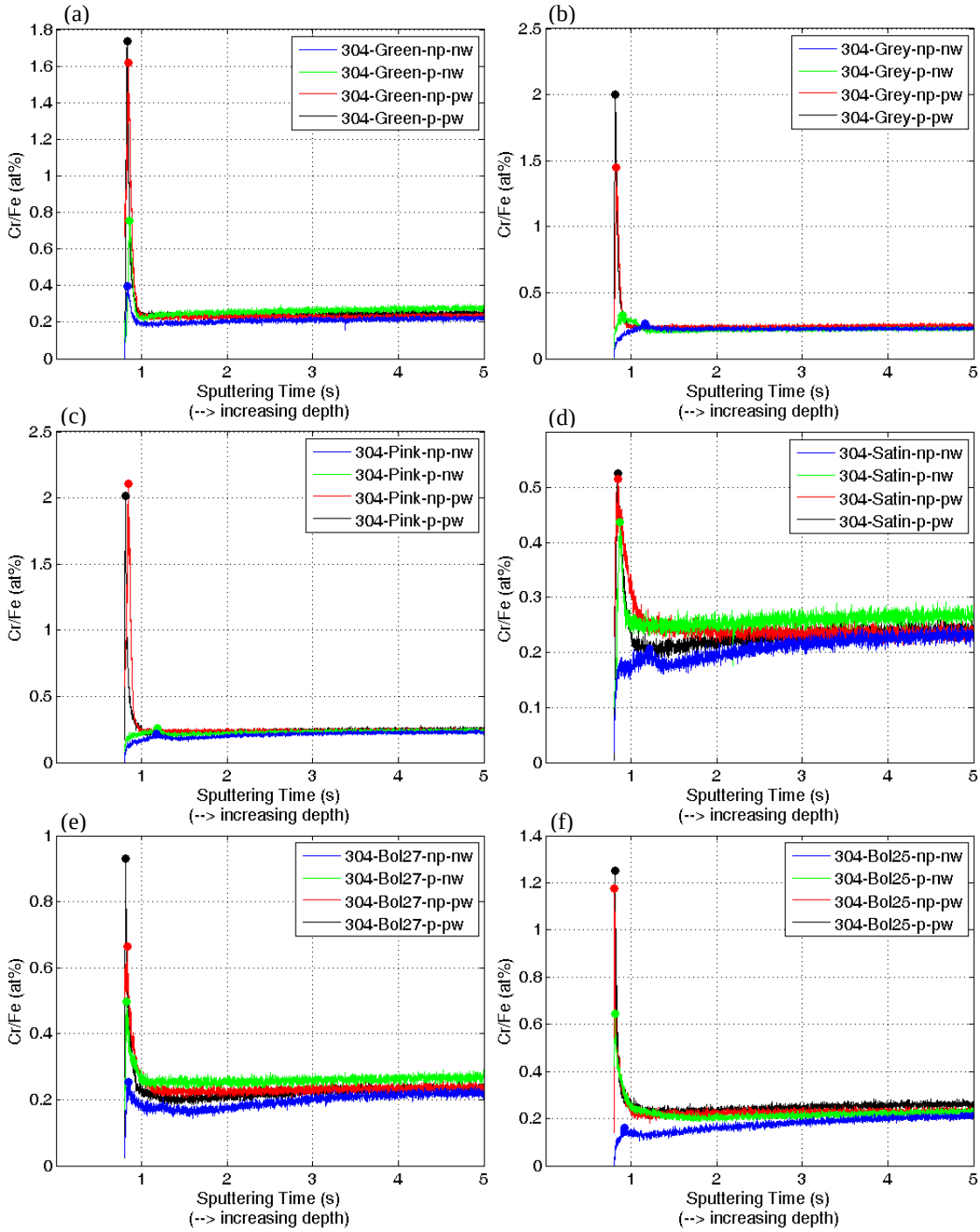


Figure 5.30 Cr/Fe ratio on all 304 samples against sputtering time, each line represents a sample set. (a) Green; (b) Grey; (c) Pink; (d) Satin; (e) Bol27; (f) Bol25;

5.3.3.1 Results of non-Passivated Unwashed Samples

It is noted that a peak value of Cr/Fe ratio can be observed for all 304-np-nw samples. After the peak and with incrementing depth, the concentration of Cr/Fe is return to its value in the bulk substrate.

A noticeable correlation between Cr/Fe peak value and roughness can be observed

from the results of 304-np-nw in Table 5.8. A decrease in Cr/Fe ratio value is noticed with the increase of roughness, although the change is not dramatic: the maximum Cr/Fe value measured is on 304-Green-np-nw with only 0.399. It indicates that the surface finishing process can naturally form a thin Chromium oxide layer on the surface. It is also seen that this effect decreases with increasing roughness.

However the peak of Cr/Fe cannot be distinguished for all samples. Where no peak is observed, the Cr/Fe ratio would gradually increase until the substrate concentration value is reached. Such a situation is only observed on matt finished, np-nw samples martensitic samples (416, 420 and 420S29). Such a situation with no Cr/Fe peak observed, it is considered that no passive film is formed on the sample surface. This is most possibly because austenitic stainless steels consists of more Cr (18-19%) than martensitic stainless steels (13-15%), and a higher concentration of Cr available in the substrates would ease the process of Cr enrichment. 416-Bol27-np-nw, as a typical example, is shown in the blue line in Figure 5.31.

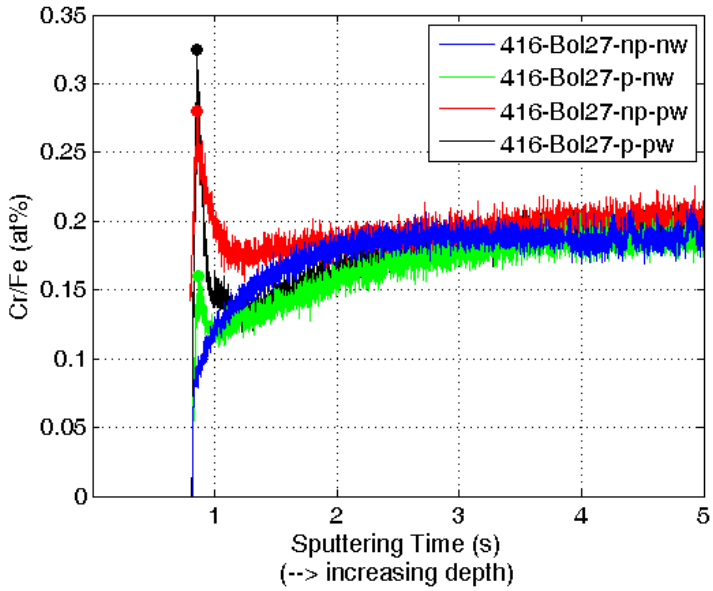


Figure 5.31 Cr/Fe ratio of 416-Bol27 samples; each line represents a sample set.

5.3.3.2 Effect Brought by Passivation and Disinfection Processes

Both passivation and disinfection processes significantly influence the peak Cr/Fe value. It is seen that in all samples after either treatment a peak was observed in the Cr/Fe ratio. Compared to 304-np-nw samples, all 304-p-nw, 304-np-pw and 304-p-pw samples show greater enrichment of Cr at the surfaces. However, the effect varies from sample to sample. For example, the Cr/Fe ratio of 304-Bol25 increased dramatically due

to passivation (from 0.161 to 0.645), while the one of 304-Pink only increased for 0.044. As a result of such variation, the effect brought by roughness can no longer be discerned in the three treated sample sets. Although a clear relationship between the peak value and roughness can no longer be seen, it is noticed that mirror-polished samples usually had a higher Cr enrichment level than rougher surfaces.

The difference between the treatments is noticeable in the absolute value of Cr/Fe ratio. Although both treatments bring an enrichment of Cr to the surface, passivation has a lesser influence. In all 304-p-nw samples' Cr/Fe ratio is elevated but still under 1. 304-np-pw and 304-p-pw samples have very similar results, with the highest Cr/Fe value observed at 2.109 (304-Pink-np-pw) and 2.015 (304-Pink-p-pw) respectively.

In summary, Cr enrichment can be observed on most samples without any treatment. This means instruments without passivation and prior to any use have a natural layer of protective film and it is denser on mirror-polished surfaces. The influence of roughness on Cr enrichment can be seen on np-nw samples but not on the other three sets. Both passivation and disinfection processes enhance the Cr enrichment at the surface, with their influences ranking as: p-pw > np-pw > p-nw.

5.4 Conclusion

From the contact angle, evaporation and Cr enrichment level measurements on various materials with different roughness and treatments, it can be concluded that:

1. There exists little difference between various stainless steel types;
2. The behaviour of surgical instruments with simply finished surfaces is greatly affected by their surface roughness;
3. Within the np-nw sample set, water droplet tends to stay most highly on Satin finished samples and least on mirror-polished surfaces;
4. On the other hand, mirror-polished samples require the longest drying time while rough surfaces the shortest;
5. Both passivation and disinfection processes lead all surfaces to behave in a similar manner, hence their behaviour is no longer affected by roughness;
6. The effect of one-year disinfection processes is more significant than 40mins passivation;
7. Polishing surgical instruments gives the surfaces a natural layer of Chromium

oxide and the effect is larger with smoother surfaces;

8. Both passivation and disinfection help in increasing the Cr enrichment level on instrument surfaces.

Chapter 6 Conclusion and Future Work

This chapter summarises the findings from the preceding chapters. It explains how conclusions can be applied to the real world situation. Potential future work is also proposed.

6.1 Conclusion

Currently there is a widespread concern regarding the quality of surgical instruments. Recent press reports pointed out a high rate of substandard surgical instruments purchased. Reported Incidents identified possible root causes including aggressiveness of disinfection processes, variety of applied surface finishes, inconsistent quality of manufacture and abnormal use.

This thesis investigated these suspected causes through three approaches: quality inspection of newly purchased instruments, root cause analysis of reported Incidents and study of the effect of surface finishes, passivation and disinfection processes with respect to their behaviour during reprocessing.

The test protocols developed and the database built have proven their worth in supervising the quality of newly bought surgical instruments. The test protocol is approved by ABHI and accepted by several manufacturers, serving as a standard for their in-house quality control. According to the inspection results recorded in the database, a high rejection rate is shown for instruments purchased for Ninewells Hospital. Identified reasons for rejection included missing or invalid regulatory marks, malfunction and manufacturing faults. Moreover, a great amount of substandard instruments are supplied by some specific manufacturers and belong to several certain instrument types. It is considered to be to some extent the result of self-declaration of Class I instruments. Therefore, it is concluded that there is an urgent need to inspect the purchased instruments and a necessity of establishing a quality-ensured list of suppliers. Changing surgical instruments from Class I to Class II should also be considered for better quality control.

It can be seen from Incidents studied that the root cause of failure of each case is

unique. Once surgical instruments are put into use, the responsibility of ensuring they remain fit for purpose is shared by surgeons, theatre staff and sterilisation services. Incidents require individual study to determine the root cause. With repeat presenting reasons, actions should be taken accordingly to reduce risks. Routine protocols can be enhanced, better design employed and harmful practices can be eliminated.

The results illustrated in Chapter 5 eliminate the suspicion of disinfection processes' aggressiveness. It is proved that the disinfection processes used in Ninewells Hospital actually enhance the corrosion resistance of surgical instruments by raising the Cr enrichment level on the surface. Passivation, having the same effect as disinfection processes, enhances the Cr enrichment level within a very short period of time and makes surgical instruments less vulnerable during their initial uses. The Cr enrichment effect is the most significant on mirror-polished samples. Moreover, the differences among various surface finishes indicate that mirror-polished surgical instruments have the poorest wettability while the Satin finished surfaces the greatest. On the contrary, mirror-polished instruments require the longest time to be fully dried while rough surfaces shorter.

To summarise these results, it can be concluded that for instruments with no large flat surfaces, mirror-polished instruments are the ideal choices. Poor wettability makes fluid such as blood less likely to stay on the instrument and a higher Cr level on the surface helps the instrument to protect itself in further use. Although mirror-polished samples require a longer drying time, instruments such as forceps and scissors allow water droplets to slip off more easily before drying. On the other hand, for instruments with large flat surfaces such as retractors and trays, reflection-reduced finishes are recommended instead of mirror-polished ones since they have less contact with aggressive solutions but contains much bigger areas for drying.

6.2 Future Work

During this project, attention has been drawn to the quality issue of surgical instruments. NHS Scotland is setting up a framework, aiming at a centralised purchasing of surgical instruments. The panel very much appreciate this study and wish to take account of the findings and advice. Therefore, efforts were made to establish a National Surgical Instrument Reference Centre (NSIRC), which would allow regular

inspection of purchased instruments and investigation of reported Incidents. However, it has been unsuccessful for multiple reasons. It has been difficult for either NHS or any funding body to support NSIRC. Although NHS Supply Chain wished to use NSIRC's service for pre-purchase quality evaluation, it was proved to be not feasible because for the NHS tender we required UKAS Accreditation which NSIRC does not possess. It was intended to seek this in the future but accreditation is expensive and an income stream was needed to support

It is suggested that for better care of surgical instruments, the purchasing of surgical instruments should change to managed contracts with approved suppliers. Quality inspection should be carried out before contract signing to ensure that all suppliers listed in the system are capable of providing quality instruments before competing on unit prices. Instruments purchased should also be inspected prior to any use and randomly during their lifecycles. Moreover, further effort should be made to establish services like NSIRC, to provide a centralised quality inspection, to analyse rejection information obtained and to investigate into reported Incidents.

In due course, the database established in this study should be expanded into a cloud service, which would allow the access of all health facilities. The test protocol should also be expanded to cover more surgical instrument types, especially the specialised ones. It is believed that the uneven quality provided by manufacturers is caused by the ease of accrediting an instrument product. Hence, efforts should be made to move surgical instruments from Class I to Class II.

The study of instruments surface finishes can be expanded as well. Currently the study is focused on the most widely applied finishes, yet it is known that other finishes are applied to surgical instruments as well, such as electropolishing. Electropolishing is considered to enhance significantly both surface smoothness and Cr enrichment level. However its effect depends on the polishing process carried out prior to it. Researches can be carried out on studying the effect of electropolishing based on different polished surfaces and comparison can be made among various electropolished surfaces and various mirror-polished surfaces.

The studied disinfection process uses alkaline detergent and is the cleaning method locally in Ninewells Hospital. Although most health facilities use detergents with similar pH value, it is known that some others use acidic ones although requests

for data proved fruitless The effect of acidic detergent on surgical instruments may be different , hence further studies should be conducted.

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Appendix A

Surgical Instruments Test Protocol: New Instruments

General Requirements

1 Markings

- Products shall be marked with the approved "CE" Mark and the name/registered trade mark of the manufacturer or the supplier.
- Product code, LOT number and UDI marked on the instrument are not yet compulsory but desirable.
- Products with tungsten carbide inserts shall have gold-coloured handles.

2 Material

- Steel used for manufacture will be of a suitable medical grade stainless. The grade shall be stated； Certificate of conformity shall be provided.
- Manufacturers should have a registered Quality Management System. The name of the holder of the QMS registration and certificate number shall be supplied.

3 Surface condition

- Products are tested visually and then at 15X magnification at working end. Images of specific interest areas are taken under up to 60X magnification.
- Products shall have no sharp edges unless required by the design of the instrument.
- Surfaces shall be free from pores, crevices and grinding marks.
- Lubricant oil at joints is desirable.
- The surface finish shall be at least one of the following: mirror-polished, reflection-reducing (satin or matt black) or a suitable applied surface coating.
- The instrument should be passivated. Confirmed by written assurance.

4 Packaging

- Each instrument shall be individually wrapped.

Function and Specifics

1 General Instruments

1.1 Scissors

- Description:

  A cutting instrument composed of two opposing blades, each having a ring-shaped handle, jointed by a pivot. Used for dissecting tissue.

- Includes (not limited to):

  Dissecting, Aufricht, Cartilage, Careless, Mayo, Cairns, Dural scissors (McKissock, Taylor), Dressing, Metzenbaum, Enucleation, Iris, Joseph, Reynolds, Stevens, Strabismus

- For micro scissors, use 1 layer of wetted tissue paper;
  For light-weight scissors, use 2 layers of Gauze or tissue paper;
  For medium-weight scissors, use 5 layers of Gauze or tissue paper;
  For heavy-weight scissors, use 8 layers of Gauze or tissue paper.
- Cut 3 times using 2/3 of the length of the cutting blade without any lateral pressure.
- The cut shall be clean without tearing.
- If tungsten carbide inserts present, welding between insert and instrument body shall have no gap.

1.2 Micro Scissors/Spring Scissors

- Description:

  A cutting instrument composed of two opposing blades, jointed by a pivot and spring-loaded at the end. Used for dissecting tissue.

- Include (not limited to):

  Vennas

- Use 1 layer of wetted tissue paper;
- Cut 3 times using 2/3 of the length of the cutting blade without any lateral pressure.
- The cut shall be clean without tearing.

1.3 Artery Forceps/Tissue Forceps /Dressing Forceps[4]/Clamps

- Description:

  A self-locking instrument with racks, serrated jaws, ring-shaped handles and a box joint. Used for grasping and compressing the end of an artery or tissue.

- Includes (not limited to):

  Artery Forceps: *Crile, Mosquito, Hoen, Adson, Dunhill, Heiss, Jolls Thyroid, Mayo, Kocher, Kelly, Mixter, Moynihan, Oschner, Ronald Edwards, Spencer-Wells, Rochester-Pean, O'Shaughnessy, Kilner, Bland Sutton*

  Tissue Forceps: *Allis, Babcock, Duval, Littlewood, Lanes, Rutherford Morison, Stiles*

  Dressing Forceps: *Bryant*

- The serrations or teeth of the jaws shall have the crests truncated and shall mesh with the opposite component.
- The racks shall close and open easily without any lateral pressure. The racks should mate accurately when engaged in order to achieve a positive lock that will not become disengaged in use. The racks shall have a smooth and gradual ride when engaged.
- When pressure on the jaws is released, serrations shall part freely without catching.
- When rack is engaged to the first or last step, it shall not open if the tip of the instrument is gently knocked on an edge of a hard surface.
- For artery forceps, place a 0.5mm diameter stainless steel wire between the tips of forceps, close the first rack. Test material should be immovable.
- For artery forceps, hold one corner of a sealed transparent plastic water bag and use instrument to clamp the water bag where has no water, fully close the racks. Water shall not leak through to the corner. When racks released, water bag shall not be punctured.
- For tissue forceps, lift a piece of printing paper by two corners and clamp

[4] Marked instruments repeatedly appear in this protocol due to different shape and structure under the same name

tissue forceps upwards on the bottom side, close the first rack and pull the instrument downwards. Test paper shall not tear apart.

1.4 Dissecting Forceps/Dressing Forceps[4]/Tissue Forceps[4]/Micro Forceps

- Description:

  A two-bladed instrument welded together at one end, with jaws on the other end smooth, serrated or toothed. Used for handling and manipulating tissues or other instruments.

- Includes (not limited to):

  Dissecting Forceps: *Adson, Bickford, Block End, Bonny, Cairns, Iris, Lanes, Canadian, Ramsey, Fine, Pennybacker, Waugh*

  Dressing Forceps: *Bayonet*

  Other: *Jefferson Dural*

- If present, teeth and prongs should be sharp and mesh exactly when the jaws are closed.
- If present, the guide pin shall be tapered to facilitate entry into the locating hole and shall not protrude beyond the hole when jaws are closed.
- When pressure is released, teeth or serrations shall part freely without catching.

1.5 Needle Holders

- Description:

  A self-locking instrument with racks, serrated jaws, ring-shaped handles and a box joint. Used for holding suturing needles.

- Includes (not limited to):

  Mayo, Hegar, Bayonet, Malis, Bozemann, Crile Murray, Crile Wood, Halsey, Kilner, Lawrance, Neivert, Ward

- The racks shall close and open easily without any lateral pressure.
- Jaws shall align precisely when closed.
- When pressure is released, jaws shall part freely without catching.
- When rack is engaged to the first or last step, it shall not open if the tip of the instrument is gently knocked on an edge of a hard surface.
- Place a 0.2mm diameter plastic test wire between the jaws of a needle

holder, fully close racks. Test material should be immovable. The test is performed, with the fibre both aligned with the longitudinal axis and at right angles to this axis.

- Each instrument shall be packaged with racks disengaged.
- If tungsten carbide inserts present, welding between insert and instrument body shall have no gap.

1.6 Self-Retaining Retractors

- Definition:

  A self-locking instrument can be used without assistance. Used for retaining incision open.

- Includes (not limited to):

  Adson, Balfour, Travers, Norfolk and Norwich, Weitlaner, West, Weislander, Mollison

- If present, the racks shall close and open easily without any lateral pressure.
- If instrument is assembled from various parts, movement between parts shall be smooth.
- When locked, the position of the instrument shall be fixed until released.
- Alternatively to being be individually wrapped the retractors can be supplied in position-fixed trays.

1.7 Other

- Definition:

  An instrument does not require any movement and whose shape cannot be changed.

- Includes (not limited to):

  Dissectors, Scalpel Handles, Retractors

- Instrument is tested against its design and all details shall match, including bending angles, direction and etc.

2 ENT & Neurosurgical Instruments

2.1 Biopsy Forceps

- Description:

  A crocodile/alligator shaped instrument, cutting with movement of the upper jaw and operated by ring-shaped handles. Used for collecting biopsies.

- Includes (not limited to):

  Kevorkian, Gerger

- The tissue cutting jaws shall mesh exactly when the jaws are closed.
- When the jaw is released, jaws shall part freely without catching.
- A plastic test sheet is placed between the jaws; the jaws are closed and then released.
- The cut shall be clean without tearing.

2.2 Ear (Aural) Forceps

- Description:

  A crocodile/alligator shaped instrument, grasping with movement of the upper jaw and operated by ring-shaped handles. Used for grasping or manipulating tissues.

- Includes (not limited to):

  Fuller, Hartmann, Henckel, Hough, Ormerod, Shea

- The serrations or teeth of the jaws shall have the crests truncated and shall mesh with its opposite component.
- Jaw movements shall match with the movements of ring-shaped handles.
- When the jaws are released, serrations shall part freely without catching.
- Place a 0.2mm diameter wire between the tips of forceps, close the jaw. Test material should be immovable.

2.3 Punch Forceps/Neuro Rongeurs

- Description:

  A crocodile/alligator shaped instrument, cutting with movement of only one jaw and operated by spring-loaded or ring-shaped handles. Used

for cutting out a disc of tissue or bone.

- Includes (not limited to):

  Punch Forceps: *Angell James, Hajek Sphenoidal, St Bartholomew's*

  Neuro Rongeurs: *Beck, Cushing, Kerrison, Pennybacker*

- The tissue cutting jaws shall mesh exactly when the jaws are closed.
- When the jaw is released, jaws shall part freely without catching.
- A plastic test sheet is placed between the jaws; the jaws are closed and then released.
- The cut shall be clean without tearing.

2.4 Scissors

- Description:

  A crocodile/alligator shaped instrument, cutting with movement of only one blade and operated by ring-shaped handles. Used for cutting tissues.

- Includes (not limited to):

  Cawthorne, Ormerod, Portmann

- Use 1 layer of wetted tissue paper;
- Cut 3 times using 2/3 of the length of the cutting blade without any lateral pressure.
- The cut shall be clean without tearing.

2.5 Other

- Definition:

  An instrument does not require any movement and whose shape cannot be changed.

- Includes (not limited to):

  Curettes, Dissectors, Elevators, Hooks, Mirrors

- Instrument is tested against its design and all details shall match, including bending angles, direction and etc.

3 Orthopaedic & Plastic Surgery Instruments

3.1 Chisels/Gouges/Osteotomes

- Definition:

  A long-bladed instrument with cutting edge bevelled on either only one side or both sides and a handle to be struck by hammers or mallets. Used for cutting bones.

- Includes (not limited to):

  Albee, Capener, Smith Peterson, Swedish

- With the instrument on a test rod at a 45° and slid along the test rod, a small amount of the material on the test rod shall be removed cleanly.
- Osteotomes shall be tested on both sides of the blade
- Alternatively to being be individually wrapped the retractors can be supplied in position-fixed trays.

3.2 Rongeurs (Bone Nibblers)

- Definition:

  A (multi)jointed, plier-like instrument with jaw opening spring. Used for breaking off pieces of bone.

- Includes (not limited to):

  Horsley, Liston, Mclndoe, Paton, Stamm, Pennybacker, Leksell, Olivecrona

- The cutting jaws shall align with each other when closed.
- When pressure is released, jaws shall part freely without catching
- A plastic test tube is placed between the jaws of the rongeur and punctured.
- Test tube shall be cut clean without tearing.

3.3 Other

- Definition:

  An instrument does not require any movement and whose shape cannot be changed.

- Includes (not limited to):

  Curettes, Elevators, Hooks, Levers, Mallets, Raspatories

- Instrument is tested against its design and all details shall match, including bending angles, direction and etc.

Appendix B
Questionnaire for Manufacturers

Dear whom it may concern,

I, Yunwei Xu, work on a project related to surgical instruments used in Scotland. I work for Prof. George Corner, head of Medical Physics of Ninewells hospital, and represent NHS Scotland as well. Here listed some questions that I would love to know. It would be great if you can get back to me ASAP.

1. Please state the name of manufacturer and supplier (if applicable)
2. Do you have your own manufacturing site/factory? If yes, please state manufacturing country.
3. Do you use subcontractors to manufacture instruments? If yes, please provide details of all.
4. Are all instruments printed with manufacturer's trade mark?
5. Are all instruments printed with a legit CE Mark?
6. Where are instruments CE marked?
7. What else information is printed on instruments? E.g. Lot No., Product code
8. What else information can be printed on instruments on demand? E.g. UDI
9. Do all instruments comply with relevant British Standards?
10. Can you provide a certificate of conformity? If yes, please provide.
11. Are the instruments surface finish treated? If yes, please detail.
12. What percentages of new instruments are inspected?

Thanks for your patience. I really appreciate it.

Regards
Yunwei Xu